

1 IN THE CIRCUIT COURT OF OHIO COUNTY
2 WHEELING, WEST VIRGINIA

3
4 IN RE:

5 TOBACCO LITIGATION CASE NO. 00-C-6000
6 MEDICAL MONITORING CASES

7
8 * * *
9

10 JURY TRIAL

11
12 Whereupon the above-entitled matter came on for
13 hearing before the Honorable Arthur M. Recht at the
14 Ohio County Courthouse, Wheeling, West Virginia, and
15 the proceedings are as follows.
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17

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19 * * *

20 VOLUME 11-A

21 October 2, 2001

22 8:30 a.m.
23

24 * * *

I N D E X

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3	NARESH C. GUPTA, M.D.	
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24 (There are other counsel representing interested
parties also present in the courtroom gallery.)

1 Tuesday Morning Session
2 October 2, 2001
3 8:30 a.m.
4 -- -- --
5 P R O C E E D I N G S
6 -- -- --
7 (In open court with a jury present.)
8 THE COURT: All right. Be seated, please.
9 Good morning.
10 MR. GRUENLOH: Your Honor, plaintiffs would
11 like to call Dr. Naresh Gupta.
12 May I introduce myself, Your Honor?
13 THE COURT: Sure.
14 MR. GRUENLOH: Ladies and gentlemen, my name is
15 Mike Gruenloh, I'm a lawyer for the plaintiffs and
16 I'm going to be putting on Dr. Gupta today.
17 THE COURT: Just step up here, sir. The young
18 lady will administer the oath to you.
19 MR. GRUENLOH: Your Honor, if I may approach, I
20 have a copy of the demonstratives we will use this
21 morning.
22 THE COURT: All right. Thank you.
23 MR. GRUENLOH: May it please the Court.
24 THE COURT: All right.

1 -- -- --
2 NARESH C. GUPTA, M.D.
3 being first duly sworn by the Clerk, testifies and
4 says as follows:

5 -- -- --
6 DIRECT EXAMINATION

7 BY MR. GRUENLOH:

8 Q. Dr. Gupta, can you please state your full
9 name?

10 A. Naresh C. Gupta.

11 Q. Could you tell the jury what your current
12 occupation is, Doctor?

13 A. I work at University of Virginia, I am
14 professor of radiology and director of nuclear
15 medicine in the PET center.

16 Q. And this is your first time testifying as
17 an expert in a trial, sir?

18 A. Yes.

19 Q. This is my first time, too, so we should be
20 on the same pace, so we will take care of each other
21 today. Where do you live, sir?

22 A. I live in [DELETED].

23 Q. Do you live there with your wife and three
24 children?

1 A. Yes.

2 Q. And where are you from originally?

3 A. I was born in New Delhi, India, and I have
4 been in this country since 1981.

5 Q. All right. You went to medical school
6 initially in New Delhi; correct?

7 A. That's correct.

8 Q. Could you tell the jury about the medical
9 school you went to in New Delhi?

10 A. The name of the school is All India
11 Institute of Medical Sciences. I was lucky to get
12 admission -- am I speaking too fast?

13 THE COURT: No.

14 A. That happens to be one of the best schools
15 in Asia. And after I finished my medical school, I
16 did three years of residency there. And during that
17 time, I took various examinations to come to this
18 country.

19 Q. What was the name of the medical school in
20 India again?

21 A. It was all India Medical Institute of
22 Medical Sciences.

23 Q. And I think you told me that in all of
24 India only forty physicians or only forty students

1 are admitted into that particular medical school; is
2 that correct?

3 A. Yes, that's correct.

4 Q. And India has got a pretty big population,
5 doesn't it, sir?

6 A. Yes, that's correct.

7 Q. You came over to the United States in 1981?

8 A. That's correct.

9 Q. Can you tell the jury a little bit about
10 the process you that went through in order to become
11 a United States citizen, the process that you and
12 your wife went through?

13 A. The initial step was obviously to pass
14 various exams, the exam was called visa qualifying
15 exam, and then ECFMG certification which qualified
16 me to come here as an immigrant at that time.

17 And then after coming here, of course, you have
18 to pass a licensure exams and get admission into a
19 residency program, which I did.

20 And after that, then, of course, when we have
21 lived here for ten years, then we applied for
22 citizenship, and I'm a citizen of this country.

23 Q. Okay. About how long did the process of
24 becoming a citizen in the United States take?

1 A. I think it took ten, fifteen years.

2 Q. You had to pass a lot of tests?

3 A. Yes.

4 Q. Okay. If you would, sir, tell us about the
5 process that you went through in order -- now, you
6 went to medical school in India initially. But then
7 when you came over to the United States, you had to
8 get licensed to practice as a physician here. Can
9 you tell us about the process that you went through
10 here?

11 A. Yes. There is, obviously, like you say,
12 there is a licensure exam, which is called a FLEX
13 exam, and you have to have residency training in an
14 approved program, which I did.

15 And then those things qualify you to apply for
16 a license, and I'm licensed in several states at
17 this time.

18 Q. Okay. Now, you said you are the director
19 of nuclear medicine at West Virginia University
20 Medical Center, and also is it a tenured professor
21 of radiology at West Virginia University?

22 A. That's correct.

23 Q. Okay. Now, as part of your clinical
24 practice, do you review low dose spiral CT scans on

1 a daily basis?

2 A. Yes, I do.

3 Q. Okay. And when I ask you about CT scans
4 during my direct examination today, sir, I want you
5 to know that I will be referring to low dose spiral
6 CT scans, because sometimes I will just say CT
7 scans; okay?

8 A. That's correct.

9 Q. And do you use CT scans in your practice
10 for the early detection of lung cancer?

11 A. Yes.

12 Q. All right. Now, I want to break down your
13 activities, your research activities, your teaching
14 activities, and your clinical practice. And I want
15 to talk about each one of those three categories
16 separately. And let's start with your teaching
17 activities.

18 Can you please tell the jury what percentage of
19 your time you spend teaching.

20 A. Well, approximately 20, 25 percent time is
21 spent in teaching, and it's been more so over the
22 last couple of years. But teaching involves
23 educational activities for the medical students,
24 residents, fellows and various training programs

1 within our medical school.

2 We have approved residency program in the
3 Department of Radiology, participate in the CME
4 conferences, and we have had a training program also
5 where we train the radiologist in the interpretation
6 of CT scans and PET scans over the last two years.

7 Q. And all of that is over at West Virginia
8 University in Morgantown?

9 A. That's correct.

10 Q. Sir, can you tell us the subjects that you
11 teach?

12 A. Well, my area of interest has been lung
13 cancer, diagnosis of lung cancer over the years.
14 And basically a lot of what I teach is the best
15 diagnosis for several cancers, including lung
16 cancer, various imaging tests which are used and
17 what is the best approach for accurate diagnosis and
18 cost-effective diagnosis.

19 Q. Okay. About how many medical students do
20 you teach on a yearly basis?

21 A. Oh, we have medical students rotate through
22 our department on a regular basis. We have
23 radiology resident all the time with me. I take
24 noon conferences, and a lot of times we have fellows

1 from other department come in and rotate through our
2 department.

3 Q. Okay. If you had to give us a number of
4 how many medical students you teach on a yearly
5 basis, would it be 40, 50?

6 A. Around, I would say, 30 to 40.

7 Q. Okay. Can you explain what it means to be
8 a tenured professor? Because you are, in fact, a
9 tenured professor of radiology; right?

10 A. That's correct.

11 Q. What does that mean?

12 A. Well, there are various ranks and steps
13 when you get an appointment in the university. I'm
14 sure most of you know about that. In the beginning
15 when you are appointed, usually starts as assistant
16 professor. And then you get promoted gradually to
17 associate professor and then full professor.

18 A tenured is a special endowment by the
19 university on you. That means you are recognized as
20 a permanent member, permanent faculty member, and
21 your contributions are valued.

22 Q. Okay. Now, you teach radiology, but you
23 are not board certified in radiology; is that right?

24 A. That's correct.

1 Q. Okay. But you do teach medical students on
2 a yearly basis on radiology?

3 A. That's correct.

4 Q. And as part of that, as part of teaching
5 them about radiology, do you teach them about low
6 dose spiral CT scans?

7 A. That's correct.

8 Q. All right. Would it be accurate to say
9 that the subject that you teach is, for the most
10 part, the detection and diagnosis of lung cancer?

11 A. Because of my personal interest and my
12 involvement in the lung cancer group, although I do
13 teach on all the cancers and various diagnostic
14 tests also.

15 Q. Let's talk about your research activities
16 for a moment. What percentage of your time would
17 you say that you spend doing research?

18 A. Approximately 25 percent.

19 Q. And have you written on the subject of the
20 diagnosis and detection of lung cancer?

21 A. Yes. I have published several articles.
22 That has been my area of interest over the last
23 decade. And I have been involved in several
24 clinical studies and several sponsored studies

1 looking at various diagnostic algorithms, and I have
2 published in those areas.

3 Q. Doctor, am I correct you have published
4 over 150 peer-reviewed articles and abstracts?

5 A. I think that's correct.

6 Q. All right. What does that mean, that it's
7 peer reviewed? Can you explain that?

8 A. Peer-reviewed journals are the journals
9 which are screened for the material that's
10 published, basically anybody who submits an article
11 with a desire to publish in a peer-reviewed journal
12 has to go through a critique process where the
13 experts in the field in which the article was
14 written will review your work, critique it and then
15 will evaluate it and give it assignment whether it's
16 worthy of publication in that journal.

17 Q. Now, you told me about one of your articles
18 that got a very prestigious award, and I think the
19 article was on the subject of the detection of lung
20 cancer. Can you tell the jury about the award that
21 that article received?

22 A. Yeah. I was fortunate, and that article
23 was published in a journal called Chest last year,
24 and that was ranked as the top ten articles in

1 diagnosis for lung cancer last year by the Moffitt
2 Cancer Center group.

3 Q. We talked about the peer-review process
4 just a second ago. Am I correct you are a peer
5 reviewer for Chest magazine?

6 A. Yes.

7 Q. Is that a pretty prestigious journal, sir?

8 A. I regard it as well regarded, I think.

9 Q. Are you also a peer reviewer for Cancer?

10 A. Yes.

11 Q. Is that a pretty prestigious journal, sir?

12 A. Yes.

13 Q. Clinical Lung Cancer?

14 A. Yes.

15 Q. The Journal of Nuclear Medicine?

16 A. Yes.

17 Q. Grant reviewer for the American Cancer
18 Society?

19 A. Yes.

20 Q. All right. Can you explain exactly what
21 that is, grant reviewer for the American Cancer
22 Society?

23 A. I was fortunate to get appointed as a grant
24 reviewer. Basically everybody knows the American

1 Cancer Society and National Institutes of Health are
2 the leading grant givers in this country. American
3 Cancer Society particularly funds highly in areas of
4 research in cancer.

5 So because of my work, I was appointed as a
6 reviewer who will review the grant proposals
7 submitted to the American Cancer Society and grade
8 them and help them decide which ones should be
9 funded.

10 Q. All right. Not everybody does that, do
11 they, sir?

12 A. No. There was a very limited board of
13 maybe only ten or twelve people.

14 Q. In the country?

15 A. Yes.

16 Q. All right. You are also a peer reviewer
17 for Annals of Pharmacotherapy?

18 A. Yes.

19 Q. You are also a peer reviewer for the
20 Journal of Pharmacy Technology?

21 A. Yes.

22 Q. And how about Clinical Nuclear Medicine?

23 A. Yes.

24 Q. All right. There is a committee that you

1 are a chairman of called the Human Use of
2 Radioisotopes and Radiation Committee. Can you
3 please explain for the jury what that committee is.

4 A. This is a radiation safety committee in the
5 West Virginia University in the Health Sciences
6 Center which reviews and approves the protocols
7 submitted for use of radioisotopes or radiation for
8 using them for patient diagnosis and patient care.

9 Q. All right. As chairman of that particular
10 committee, is one of your duties to ensure that you
11 are up to speed, that you know about all the
12 literature on the safest and most state of the art
13 diagnostic and detection equipment for lung cancer?

14 A. Yes.

15 Q. All right. You are also a member of the
16 Society of Nuclear Medicine; right?

17 A. Yes.

18 Q. Can you tell the jury what that society
19 does?

20 A. The Society of Nuclear Medicine is a
21 national society for which encourages research and
22 educational and clinical activities in the field of
23 imaging, diagnostic imaging, various radioisotopes.
24 That's the field of nuclear medicine.

1 Q. Does that include CT scans, sir?

2 A. It correlates all those studies with CT
3 scanning.

4 Q. Okay. You are also chairman of the
5 committee called the Educational and Research
6 Foundations Pilot Research Grant Committee. What is
7 that?

8 A. Society of Nuclear Medicine has an
9 educational and research foundation, which is
10 overseeing and heading the various educational
11 research activities within the Society of Nuclear
12 Medicine.

13 And a part of that is a part of research grant
14 committee which I chair, again, which has a role of
15 reviewing and approving the grant proposals and
16 deciding which grant proposals or research proposals
17 are worthy of funding.

18 Q. Now, you have also been an invited speaker
19 to many national meetings on the subject of the
20 detection of lung cancer; correct, sir?

21 A. More than I can attend, yes.

22 Q. You have actually been a chairperson or a
23 moderator for many of those meetings, haven't you?

24 A. Yes.

1 Q. All right. And that's quite a distinction;
2 isn't it, sir?

3 A. I consider that, because that's purely by
4 appointment by your peers.

5 Q. What do you do as a chairman or moderator
6 of a national meeting on the detection of lung
7 cancer?

8 A. Basically you coordinate and you oversee
9 the various scientific papers presented. The chairs
10 that I have usually -- sessions which I have usually
11 chaired are on lung cancer diagnosis.

12 So the moderator has the responsibility of
13 making sure everything goes smoothly and provides
14 expert comments in terms of the state of the art in
15 that particular field for the benefit of all the
16 audience.

17 Q. All right. We have heard a lot about
18 Dr. Claudia Henschke in this trial. You have
19 actually been a moderator or a chairperson of some
20 of the national meetings where her papers were
21 presented; is that right, sir?

22 A. That's correct.

23 Q. All right. You have actually met
24 Dr. Henschke, haven't you?

1 A. Yes, we have. And I have attended
2 conferences, yes.

3 Q. Have I missed anything on your research
4 activities before we move on?

5 A. No, pretty much, I think, we covered it.

6 Q. All right. Let me ask you before we move
7 on, would it be accurate to say that the focus of
8 your research activities is on the early detection
9 of lung cancer?

10 A. That is true.

11 Q. All right. And how long has that been a
12 focus of your research activities?

13 A. Last ten to twelve years.

14 Q. I want to talk now about your clinical
15 practice. You see patients. And as I added up
16 the -- you spend about 25 percent of your time on
17 research, you spend about 25 percent of your time
18 teaching, so is it fair to say you spend the other
19 half, about 50 percent of your time, seeing
20 patients?

21 A. Yes. As much as, even though numbers may
22 sound more than 100 percent, but it's 50 to 60
23 percent.

24 Q. Okay. You are the director of the nuclear

1 medicine program at West Virginia University;
2 correct?

3 A. That's correct.

4 Q. All right. Can you explain what your
5 duties entail as the director.

6 A. Making sure all the diagnostic studies are
7 done, taking into account all of the state of the
8 art recommendations, provide the best state of the
9 art imaging facilities for the best patient care.

10 Q. By the way, what does the field of nuclear
11 medicine entail? Give us some examples of what that
12 would include.

13 A. Yeah. Nuclear medicine would include PET
14 scanning, bone scans, thallium scans.

15 Q. Do you also look at CT scans?

16 A. We always correlate the CTs, and we have a
17 program correlating various diagnostic tests, like
18 CT scans, x-rays.

19 Q. All right. There is something, the West
20 Virginia University Medical Center called the
21 Comprehensive Lung Cancer Program. Can you explain
22 what that is.

23 A. Yes. Within the cancer center, over the
24 last few years, they have formed a comprehensive

1 lung cancer program which is basically a
2 multidisciplinary program which brings together
3 physicians from various disciplines, like surgery,
4 we have thoracic surgeons with us, we have radiation
5 oncologists, we have medical oncologists, we have
6 pulmonary physicians, we have diagnostic
7 radiologists, we have nuclear medicine people,
8 So they all come together and provide and
9 interact with each other to come up with the best
10 ways to provide patient care who have lung cancer or
11 who have suspected lung cancer.

12 Q. All right. So you get a big room full of
13 doctors from every discipline basically, and you
14 talk about how to detect, diagnose and treat lung
15 cancer patients; is that right?

16 A. Yeah. We do that once a week.

17 Q. What day of the week do you do that?

18 A. In fact, today at 4:00 I'm supposed to be
19 there.

20 Q. We will try to get you out of here in time
21 for you to go to your meeting.

22 Is one of your duties on that committee
23 ensuring, that you are using at West Virginia
24 University Medical Center, the most state of the art

1 detection equipment for lung cancer?

2 A. That's correct.

3 Q. All right. Is one of the modalities or one
4 of the pieces of equipment that you use there low
5 dose spiral CT scan?

6 A. Yes.

7 Q. Doctor, would it be accurate to say that
8 the focus of your clinical work is also the early
9 detection of lung cancer?

10 A. Yes.

11 Q. Do you also participate in the treatment of
12 lung cancer patients once they are actually
13 diagnosed with lung cancer?

14 A. Yes. As a part of the lung cancer group,
15 we all interact and come up with the best diagnosis
16 of the patients, putting all of the data together,
17 and then, as a team, we come up with the best
18 approach for the treatment of the patients.

19 Q. Can you give me an estimate of the number
20 of lung cancer patients that you have diagnosed in
21 the State of West Virginia with lung cancer?

22 A. Again, it would be an approximation because
23 I have not had it counted. But I would say anywhere
24 from fifteen hundred to two thousand.

1 MR. GRUENLOH: Your Honor, at this time the
2 plaintiffs would offer Dr. Gupta as an expert in the
3 early detection and diagnosis of lung cancer.

4 MR. WOODSIDE: May we approach?

5 THE COURT: All right.

6 (At sidebar:)

7 MR. WOODSIDE: Your Honor, I don't have any
8 objection to that designation. I'm not certain
9 exactly what it entails, so I would reserve the
10 right to cross-examine him on his qualifications and
11 challenge his opinions at a later point in time.

12 THE COURT: In cross-examination?

13 MR. WOODSIDE: Yes, sir. And I just wanted to
14 make sure I am not waiving anything by doing it.

15 THE COURT: You are not waiving anything.

16 MR. WOODSIDE: Thank you.

17 (In open court:)

18 THE COURT: All right. Dr. Gupta will be
19 considered as an expert witness capable of giving
20 opinions and conclusions within the field of
21 medicine generally and the early detection and
22 diagnosis of lung cancer.

23 Are you offering him up also as an expert in
24 radiology?

1 MR. GRUENLOH: We are not specifically in
2 radiology, Your Honor. Just the early detection and
3 diagnosis of lung cancer.

4 THE COURT: All right. That's fine.

5 MR. GRUENLOH: May I approach the witness, Your
6 Honor?

7 THE COURT: Sure.

8 MR. GRUENLOH: Here you go, Doctor.

9 THE WITNESS: Thank you.

10 MR. GRUENLOH: You have seen this chart before,
11 Mr. Woodside?

12 MR. WOODSIDE: Yes, I have, Mr. Gruenloh.
13 Thank you.

14 BY MR. GRUENLOH:

15 Q. Doctor, for all of the questions that I
16 will be asking you today, I would ask that you give
17 your opinion to a reasonable degree of medical
18 certainty. Can you do that for me, sir?

19 A. Yes.

20 Q. All right. This is a chart that Mr. Segal
21 used in his opening statements, and I'm going to ask
22 you -- I'm going to focus on Question No. 6 today,
23 Doctor. That reads:

24 The monitoring procedures exist that make

1 the early detection of disease possible.

2 And I'm going to narrow that further, and the
3 only disease I'm going to ask you about today is
4 lung cancer; okay?

5 A. All right.

6 Q. As a physician who specializes in the
7 detection and diagnosis of lung cancer, is the early
8 detection of lung cancer the focus of what you do,
9 sir?

10 A. That's correct.

11 Q. All right. And if a patient gets lung
12 cancer, is there anything more important than the
13 early detection of the lung cancer?

14 A. That's the most important thing so far
15 that's been proven to save lives in lung cancer.

16 Q. All right. Now, based upon your education,
17 your training and, most importantly, your experience
18 of diagnosing, I think you said two thousand some
19 patients in West Virginia with lung cancer, I want
20 to know: Do CT scans, low dose spiral CT scans make
21 the early detection of lung cancer possible?

22 A. Yes.

23 Q. Is lung cancer a latent disease?

24 A. Unfortunately, it is.

1 Q. All right. Can you tell me how many cases
2 of lung cancer you diagnosed last year alone?

3 A. Oh, new cases -- we see a lot of cases
4 being treated. But just looking at the new cases,
5 around 250.

6 Q. All right. Can you give me some idea of
7 how that compares with the number of cases that you
8 diagnosed, say, in 1995 in West Virginia?

9 A. The numbers have been increasing. I think
10 it started with 150 at that time.

11 Q. So you had 150 in 1995 and about 250 last
12 year?

13 A. That's correct.

14 Q. All right. So you are actually seeing more
15 lung cancer than you have ever seen before?

16 A. That's correct.

17 Q. When you diagnose a patient, do you
18 ordinarily know whether or not the patient was a
19 smoker?

20 A. Yes.

21 Q. And Doctor, can you tell the jury, of the
22 two thousand patients that you have diagnosed with
23 lung cancer, how many of them were never smokers,
24 had never smoked a cigarette?

1 A. Hardly, very rarely.

2 Q. When you see a patient, do you ordinarily
3 tell them, if the patient is, in fact, a smoker, do
4 you tell them to quit smoking?

5 A. We all make it a point to stress that.

6 Q. Okay. Does quitting smoking make the
7 detection of lung cancer possible? Does that have
8 anything to do with that, sir?

9 A. That's kind of a strange question because
10 quitting smoking is a habit, and diagnosis is a
11 diagnostic test. So there is no link between the
12 two.

13 Q. Doctor, have you prepared a slide on the
14 stages of lung cancer?

15 A. Yes.

16 Q. Do you believe that that will assist the
17 jury this morning?

18 A. Yes.

19 MR. GRUENLOH: Gina, would you please put up
20 that first demonstrative.

21 BY MR. GRUENLOH:

22 Q. Doctor, using this slide -- and I see you
23 have got your pointer with you, first of all, if you
24 could explain the slide and then, if you would, sir,

1 please explain the stages of lung cancer.

2 A. Like you mentioned, the lung cancer,
3 unfortunately, is a latent disease, and it often is
4 detected very late. But if you look at the biology
5 and what happens and how does cancer start, usually
6 it starts obviously with a single cell in the
7 beginning, and then you have doubling times.
8 Doubling times means one cell becomes two, two
9 becomes four, four becomes eight, and the cells keep
10 on multiplying.

11 And with that multiplication, the size
12 increases. So with the ten doubling, then you have
13 a size which you would say early stage or Stage 1
14 lung cancer.

15 Stage 1 is where it's still localized within
16 the lung, has not spread to the lymph nodes. There
17 are several lymph nodes close to the midline inside
18 the chest around the important structures. So Stage
19 1 is still localized in the lung, and that is at the
20 time when you have the best hope for cure if it's
21 taken out of the chest at that time.

22 Now, if nothing is done, obviously the cancer
23 will keep on growing, and there will be several more
24 doubling times. And eventually it may enter a Stage

1 2.

2 And at that time, the size has increased
3 proportionately where it has started to slowly
4 spread to the surrounding tissues, and it may still
5 not be visible somewhat to a chest x-ray. It keeps
6 on growing, and this is the stage when it first
7 becomes visible if someone were to do chest x-ray.

8 But at this particular size, there is very high
9 risk that the cancer has already spread to the lymph
10 nodes within the chest. That means it might be
11 Stage 3 at that time.

12 Q. Doctor, let me stop you for a second
13 there. Is that the stage at which most lung cancers
14 become what we call symptomatic?

15 A. Yes. Unfortunately, nearly 70 percent of
16 the lung cancers, when the patients first present,
17 have complaints about lung cancer, come to the
18 physicians, that is the stage when they are in.

19 So that is most of the time when the cancer is
20 first detected, provided the patients come
21 themselves to the physicians, and the diagnostic
22 tests don't go to the patients.

23 So and, unfortunately, most of the time at this
24 stage, 70 to 80 percent of the time the cancer is

1 not curable. That means, even if you take it out,
2 you will not root out the cancer.

3 Q. All right. I'm sorry for the
4 interruption. Go ahead.

5 A. So that's the Stage 3, and obviously if
6 nothing is done, it keeps on growing. And remember,
7 the growth is not linear. That's because one
8 becomes two, two become four, four become eight. So
9 as the number of cells are growing, their later
10 growth keeps on getting bigger and bigger, so -- and
11 if nothing is done at this time, obviously the
12 unavoidable end point would be the death
13 unfortunately.

14 Q. Okay.

15 MR. GRUENLOH: Gina, you can take that down.
16 Thank you.

17 BY MR. GRUENLOH:

18 Q. Doctor, is this about the size of most lung
19 cancer tumors when they become symptomatic, when
20 they start causing some of the symptoms?

21 A. Roughly that would be a good comparison,
22 that's the size when they would be picked up on
23 chest x-ray.

24 THE COURT: What are you using? The record

1 won't pick up when you say this.
2 MR. GRUENLOH: Thank you, Your Honor.
3 I'm using a half dollar; I'm holding up a half
4 dollar, Doctor.
5 BY MR. GRUENLOH:
6 Q. And Doctor, I'm holding up the head of an
7 eraser now. And let me ask you, is this about the
8 size of most lung cancer tumors that can be detected
9 by CT scans?
10 A. Yes. CT scanning is very, very sensitive.
11 It picks up even one- or two-millimeter nodules.
12 Q. All right. Would this be a Stage 1 lung
13 cancer, Doctor?
14 A. Yes, very early.
15 Q. All right. And if you had to put a stage
16 on it, would the half dollar, what stage would that
17 be?
18 A. That's getting near to Stage 3, 2 or 3.
19 Q. Okay. Tell me what resection means.
20 A. Resection is taking out of the cancer in
21 entirety from the body. So the tumor can be shut
22 out in total and removed from the body.
23 Q. Is that about the only cure for lung cancer?
24 A. That is the treatment that offers the best

1 chances for survival in lung cancer.

2 Q. And I'm holding up the half dollar again,
3 Doctor. Is a lung cancer tumor the size of a half
4 dollar, this big, is that resectable?

5 A. Most of the time, it's too late.

6 Q. All right. And I'm holding up the eraser
7 head again, and I want to ask you, Doctor, is a lung
8 cancer tumor this size, is that resectable?

9 A. Most of the time, it will be resectable.

10 Q. Before we talk about CT scans more in
11 depth, let me ask you, you are considered one of the
12 pioneers of a new technology called PET scan, that's
13 P-E-T; is that correct, sir?

14 A. That's correct.

15 Q. Can you explain to the jury what a PET scan
16 is, P-E-T?

17 A. PET scan stands for positron emission
18 tomography. It's one of the latest generation
19 diagnostic tests that are now very popular, used in
20 most of the centers, most of the big centers and
21 ever spreading to the small centers around the
22 country, because it has very high specificity.

23 It's not as sensitive as CT scanning, but,
24 after a nodule or lesion has been seen on CAT scan,

1 then it's used after that to tell whether it's
2 cancer or not.

3 Q. And when we say you are one of the pioneers
4 of PET scanning, what does that mean?

5 A. We were the first one to use it in the
6 diagnosis of lung cancer in the world, and it was
7 first presented, our results, in 1990.

8 Q. All right. Just so we are very clear on
9 this, Doctor, you understand that the plaintiffs in
10 this case are asking only for an annual low dose
11 spiral CT scan on an annual basis for lung cancer
12 detection. You understand that, sir?

13 A. That's correct.

14 Q. All right. And we will talk more about
15 this later, but I want to ask you, in your opinion,
16 is one annual CT scan, low dose spiral CT scan,
17 without a PET scan or any other procedure to confirm
18 the diagnosis or anything else like that, is that,
19 one annual CT scan, enough to make the early
20 detection of lung cancer possible?

21 A. Yes.

22 Q. All right. Let's go ahead and talk about
23 CT scans then, and just to put this in a little
24 context, I would like you to talk about x-rays

1 first. Have you prepared a slide of a woman getting
2 an x-ray?

3 A. Yes.

4 Q. All right.

5 MR. GRUENLOH: Ms. Gina, could you please put
6 that up? Thank you.

7 BY MR. GRUENLOH:

8 Q. Doctor, could you please tell the jury what
9 is going on in this slide.

10 A. This is a figure explaining in simple
11 graphics how a chest scan, chest x-ray is obtained.
12 There is basically you have a tube and detector. So
13 the x-ray tube gives out the radiation, and there is
14 a detector with a film in front of the patient.

15 This is how a chest P.A., or posterior anterior
16 view, is obtained. That's the most traditional way
17 of doing a chest x-ray, how it is done. And it
18 takes a few seconds.

19 Q. Okay. And chest x-rays have been around
20 for a pretty long time, haven't they, sir?

21 A. Yeah. Early 1900s.

22 Q. Okay. Have you also prepared a slide
23 showing a CT scanner?

24 A. Yes.

1 Q. All right.

2 MR. GRUENLOH: Gina, could you please put up
3 that slide? Thank you.

4 BY MR. GRUENLOH:

5 Q. Doctor, is this a low-dose spiral CT
6 scanner?

7 A. Yes. It's one of the CT scanners we can do
8 helical spiral CT, very fast.

9 Q. First of all, I would like you, if you
10 could, to explain to me how this machine works.

11 A. Basically again, you have several x-ray
12 tubes and detectors which rotate, which make it
13 possible to obtain information in spiral form so
14 there is a 3-D volume data collection. That's why
15 it's possible, like, to do a chest CT in a few
16 seconds.

17 That's basically what the procedure is.

18 Q. All right. You said it only takes -- how
19 long does it take to do the procedure?

20 A. At the most, less than a minute.

21 Q. Okay. And when we say "low dose spiral CT
22 scans," what does the term "low dose" refer to?

23 A. We use low dose of the amperage or of the
24 current in the x-ray tube, and that is very low

1 radiation exposure to the patient.

2 Q. All right. Is the radiation exposure that
3 a patient gets when they get a low dose spiral CT
4 scan similar to the radiation that a patient would
5 get, say, in an x-ray?

6 A. Yeah, pretty comparable. Another way of
7 looking at it is, if somebody were to fly from New
8 York to San Francisco in a plane, you might get that
9 much radiation.

10 Q. Are low dose spiral CT scans more sensitive
11 than x-rays?

12 A. No question about that.

13 Q. All right. Have you prepared a slide,
14 Doctor, which compares a CT scan with an x-ray?

15 A. Yes.

16 Q. All right. Do you believe that that will
17 help assist the jury?

18 A. Yes.

19 MR. GRUENLOH: Gina, could we please see that?
20 All right.

21 BY MR. GRUENLOH:

22 Q. First of all, Doctor, could you please
23 explain what's on the top there.

24 A. This is a patient's chest x-ray -- thank

1 you. This is posterior anterior chest x-ray of the
2 patient.

3 Q. And I'm sorry, this is one of your
4 patients?

5 A. Yes. This is one of our patients which was
6 being worked up for incidentally. And the chest
7 x-ray did not show any abnormality.

8 Q. All right. And the CT scan, Doctor, is
9 that from the same patient at about the same time?

10 A. Same patient had a CT scan done within a
11 week of the chest x-ray. And you can -- you can
12 clearly see, everybody can see, the abnormal whitish
13 area that's the dense nodule in the right lung,
14 which is clearly not seen on chest x-ray.

15 Q. Okay. Now, just so we are clear, Doctor,
16 the x-ray is a picture, the x-ray and CT are
17 pictures of the same person's chest that were taken
18 within a week of one another; is that correct?

19 A. That's correct.

20 Q. And, if you had only the x-ray upon which
21 to base your opinion as somebody who specializes in
22 the early detection of lung cancer, and the person
23 was asymptomatic for any disease, and you looked at
24 only that x-ray, what would your conclusion, if any,

1 be?

2 A. This is a normal chest x-ray.

3 Q. What would you do that with that patient?

4 A. That patient might be sent home, if the

5 patient does not have symptoms.

6 Q. All right. Now, let's focus on the CT scan
7 which you said was taken within a week of the x-ray,
8 the same patient. Can you point out again what this
9 is?

10 A. This is a solitary pulmonary nodule,
11 basically a nodule in the right lung. What that
12 means is this is clearly abnormal; it's an abnormal
13 finding. And this needs to be worked up and could be
14 cancer.

15 Q. Let me ask you the same question I asked
16 you a moment ago about the x-ray, but with respect
17 to the CT scan. That is: If you had an
18 asymptomatic patient, and you had only this CT scan
19 upon which to base your conclusion, as someone who
20 specializes in the early detection of lung cancer,
21 what would your conclusion be?

22 A. This patient has roughly 40, 50 percent
23 chance of having lung cancer, so you have to work up
24 the patient for possible lung cancer.

1 Q. Did this, in fact, end up being lung
2 cancer?
3 A. Unfortunately. Yes.
4 Q. What stage lung cancer is that right there?
5 A. This was Stage 1, Stage 2.
6 Q. All right. Now, had you not had the CT
7 scan, would you have sent that patient home, if you
8 had only the x-ray to base your conclusion on?
9 A. This would have been undetected, yes.
10 Q. After you found that nodule -- is that what
11 you called it a nodule?
12 A. Yes.
13 Q. That just means a tumor; right?
14 A. Yes.
15 Q. After you found that in the CT scan, can
16 you tell me what you did?
17 A. This patient then underwent a PET scan --
18 that is the standard of care in our institution and
19 a lot of big centers around the country -- to see if
20 this nodule, in fact, is cancerous or because you
21 can have benign, benign meaning things which are not
22 cancer, you can have similar findings on a CT scan.
23 Q. The PET scan what you talked about a little
24 earlier, the one you kind of started in West

1 Virginia; right?

2 A. Yes. And that showed that this lesion was
3 actually cancer.

4 Q. All right. So after you took -- after you
5 took the PET scan, that confirmed that it was, in
6 fact, lung cancer; right?

7 A. Yes.

8 Q. All right. Let me ask you. After you
9 found this tumor on the CT scan, you didn't go do a
10 thoracotomy on the patient, did you?

11 A. No. Usually we don't do that.

12 Q. You didn't go do a biopsy on the patient,
13 did you?

14 A. No. Usually the standard of care is to do
15 a PET scan in our institution.

16 Q. All right. And when you say "standard of
17 care," what do you mean by that?

18 A. That's the recommended best way to diagnose
19 lung cancer.

20 Q. Is there any reason you can think of that
21 your fellow West Virginia physicians would not be
22 able to follow that standard of care to confirm a
23 diagnosis of lung cancer once they find a positive
24 result on CT scan?

1 A. No.

2 MR. WOODSIDE: Objection. No foundation. Move
3 to strike.

4 THE COURT: The objection will be sustained.
5 And the response of Dr. Gupta will be stricken. The
6 jury will be asked to disregard it.

7 MR. GRUENLOH: All right.

8 BY MR. GRUENLOH:

9 Q. Doctor, let me ask you this. You
10 understand, as we talked about earlier, that the
11 only test with respect to lung cancer that the
12 plaintiffs are asking for in this case is a low dose
13 spiral CT scan; correct?

14 A. Yes.

15 Q. All right. Is the low dose spiral CT scan,
16 that picture on the bottom, is that what made the
17 early detection of lung cancer in that patient
18 possible?

19 A. Yes.

20 Q. In your experience, is it common for x-rays
21 to miss small Stage 1 lung cancer tumors like the
22 one that's picked up on the CT scan?

23 A. Yes. Most of the nodules smaller than one
24 and a half centimeter will be missed on chest x-ray.

1 Q. All right. Now, a couple of terms have
2 already been used in this trial, sensitivity and
3 specificity, and I wonder if you could explain to
4 the jury what the difference between those two terms
5 is?

6 A. Sensitivity means what percentage of, for
7 example, a hundred cancers will be detected using a
8 particular test. Like, if a test shows you cancer
9 in 90 patients out of a hundred, the sensitivity is
10 90 percent.

11 On the other hand, if a test picks up cancer in
12 all hundred patients which actually have cancer,
13 that will be 100 percent sensitivity.

14 Q. All right. For a test to pick up lung
15 cancer, do you want it to be a pretty sensitive test?

16 A. Yes.

17 Q. And why is that, sir?

18 A. Because the goal here is not to miss any
19 early lung cancer.

20 Q. Let me show you a chart that Mr. Woodside
21 actually used in his opening statements.

22 MR. GRUENLOH: Gina, do you have that chart for
23 me, please? Thank you.

24 BY MR. GRUENLOH:

1 Q. I just want to ask you a couple of
2 questions about this, sir. It reads at the top
3 "Spiral CT Is Not Safe." Do you agree that spiral
4 CT is not safe?

5 A. It's well regarded as one of the safest
6 tests.

7 Q. And you use it now, don't you?

8 A. Every day.

9 Q. All right. And it says:

10 False positives lead to unnecessary and
11 traumatic follow-up tests: Bronchoscopy,
12 biopsy and thoracotomy.

13 First of all, what's a false positive?

14 A. A false positive, if a test tells you a
15 patient has lung cancer, and the patient actually
16 did not have lung cancer.

17 Q. In your experience over the last couple of
18 years, Doctor, how many times have you done a
19 bronchoscopy, a biopsy or a thoracotomy on a patient
20 who does not, in fact, have lung cancer?

21 MR. WOODSIDE: Your Honor, I'm going to
22 object. There has been no foundation that this
23 physician does those procedures.

24 THE COURT: Well, the objection will be

1 sustained. You can reframe the question.

2 MR. GRUENLOH: I will lay the foundation, Your
3 Honor.

4 THE COURT: I mean, has he recommended it?

5 BY MR. GRUENLOH:

6 Q. Doctor, if you find a positive result on a
7 CT scan like we found before, there are certain
8 tests that can be done to, in fact, confirm the
9 diagnosis of lung cancer; correct?

10 A. Yes.

11 Q. All right. And we talked about the
12 comprehensive lung cancer program before that you
13 are a member of; right?

14 A. Yes.

15 Q. All right. Is one of the things that you
16 do as a member of that comprehensive lung cancer
17 program over at West Virginia University Medical
18 Center to meet with -- meet in that big room full of
19 physicians and determine whether somebody who has a
20 positive result on a CT scan should get one of those
21 three tests up there?

22 A. Yes. We recommend and we follow up the
23 patients so that we all suggest what is the best
24 available workup for those patients.

1 Q. And of the two thousand patients that you
2 mentioned earlier that you have, in fact, diagnosed
3 with lung cancer over the last however many years in
4 West Virginia, have you been, at least in part,
5 responsible for recommending whether they should get
6 one of those procedures?

7 A. Yes.

8 Q. All right. Can you tell me, of the two
9 thousand lung cancer -- two thousand some odd lung
10 cancer patients you have diagnosed in the State of
11 West Virginia, how many of them have gotten a
12 bronchoscopy, a biopsy or a thoracotomy and did not,
13 in fact, have lung cancer?

14 A. Well, first thing, the things that really
15 change over the years, like I said, for the last
16 four or five years, and especially in last couple of
17 years, the standard of care has really been not to
18 rush for surgery as soon as you have an abnormal CT
19 scan.

20 In other words, if a CT scan is positive, you
21 don't take the patient directly to surgery. It's a
22 standard of care in our institution to do a PET
23 scanning first.

24 It's a noninvasive test which provides you 95

1 percent accuracy whether this is going to be cancer
2 or not. And that really minimizes unnecessary
3 biopsies and procedures in patients which actually
4 don't have lung cancer.

5 Q. Doctor, while we are talking about false
6 positives, let me ask you, do you have clinical
7 experience with breast cancer screening and prostate
8 cancer screening?

9 A. Yes.

10 Q. Do false positives occur when you screen
11 for breast cancer?

12 A. There are quite a few false positives, yes.

13 Q. Do false positives occur when you screen
14 for prostate cancer?

15 A. Yes.

16 Q. All right. For both of those types of
17 cancer, is screening done routinely in the United
18 States right now?

19 A. Yes. That's the recommended procedure.

20 Q. All right. Are you familiar with the
21 literature that discusses false positives in the
22 screening of those two diseases?

23 A. Yes.

24 Q. Have you helped prepare a slide which

1 discusses some of that?

2 A. Yes.

3 MR. GRUENLOH: Gina, could you please put up
4 the Petty article?

5 BY MR. GRUENLOH:

6 Q. All right. Doctor, first of all, let me
7 ask you, have you reviewed this article before?

8 A. Yes.

9 Q. And this is an article by Dr. Thomas Petty
10 entitled "It's Time To Pick The Low Hanging Fruit."
11 If you could blow that up for me, Gina.

12 It appeared in Chest magazine. You are a peer
13 reviewer of that magazine; right?

14 A. Yes.

15 Q. And you also get that magazine; right?

16 A. Yes.

17 Q. And it was published in January of 2000?

18 A. Yes.

19 Q. Is this the type of article that physicians
20 such as yourself who specialize in the early
21 detection of lung cancer would rely upon to form a
22 basis of your opinions?

23 A. Yes.

24 Q. And have you, in fact, relied upon this

1 article to form a basis of your opinion?

2 A. Yes.

3 Q. All right. Doctor, the part of this
4 article that I have blown up reads:

5 When lung cancer is diagnosed in early
6 stages, the survival is excellent. This is the
7 case for other common cancers, such as breast,
8 colon, uterine and prostate cancer, all of
9 which are aggressively pursued by appropriate
10 screening techniques where reimbursement is no
11 longer a question. We need the same for lung
12 cancer.

13 First of all, do you agree with that?

14 A. Yes.

15 Q. A very recent study offers a pragmatic
16 approach to lung cancer screening via high-
17 resolution CT scanning. The yield rate of
18 diagnosis of small noncalcified malignant
19 lesions --

20 What are they?

21 A. Malignant lesions is a cancer.

22 Q. All right.

23 -- was increased fourfold over standard
24 chest radiology.

1 Is what they are saying that CT scans pick up
2 lung cancer nodules four times better than x-rays?

3 A. That's correct.

4 Q. All right.

5 When early small lesions are resected,
6 the survival can be greater than 80 percent.

7 A. That's correct.

8 Q. Can you please tell the jury the
9 significance of that statement?

10 A. Well, the goal of best managing lung cancer
11 patient is to pick it up very early, as I said.
12 Your best bet in saving lives with a patient with
13 lung cancer is to detect it very early on because,
14 only when it is picked up very early on, you can
15 have survival of 70 or 80 percent. But, if you wait
16 and it's not picked up very early on, survival falls
17 down to as low as 10 to 15 percent.

18 Q. Is that, in fact, what the national average
19 mortality is for lung cancer in this country?

20 A. Five-year survival in this country is 10 to
21 15 percent for lung cancer.

22 Q. Why is that?

23 A. Because most of the cancer is detected very
24 late.

1 Q. And when it is detected late, how does that
2 impact upon whether or not you can cure the cancer?

3 A. You can take it out surgically. So you can
4 only cure the symptoms. You can't cure the root
5 cause of the cancer.

6 Q. All right. I'm going to show you another
7 article, Doctor, that you reviewed.

8 MR. GRUENLOH: Gina, will you please put up the
9 Bittner article. Thank you.

10 BY MR. GRUENLOH:

11 Q. Doctor, first of all, this is an article
12 entitled "CT Screening Offers New Options For
13 Radiology." It's offered by Craig Bittner.

14 And could you blow that up? It's on there
15 somewhere. I think it's at the bottom, actually. A
16 little bit over. Well, we can read it from there.

17 That appeared in Diagnostic Imaging in 2001.
18 Have you read that article, Doctor?

19 A. Yes.

20 Q. All right. Is this the type of article
21 that physicians such as yourself who specialize in
22 the early detection of lung cancer would rely upon
23 to form a basis of your opinions?

24 A. Yes.

1 Q. And have you, in fact, relied upon this
2 article to form the basis of your opinions in this
3 case?

4 A. Yes.

5 Q. All right. The part that we have blown up
6 here reads:

7 Although the utility of mammography and
8 prostate-specific antigen screening remains a
9 subject of discussion, the scientific evidence
10 of for the heart scan, the lung scan, and
11 virtual colonoscopy already exists. They can
12 save lives.

13 First of all doctor, what does he mean, lung
14 scanning?

15 A. The CT scanning for lung cancer.

16 Q. That's what he's talking about in that
17 article?

18 A. That's correct.

19 Q. Do you agree that the lung scan can save
20 lives?

21 A. Yes.

22 Q. For those who doubt the lung scan, again,
23 the numbers are clear. While skeptics decry a
24 lead bias or length bias, that same argument

1 can be made for breast cancer, and no one is
2 about to stop mammographic screening.

3 Do you agree with that?

4 A. Yes.

5 Q. The lung scan has turned the numbers
6 upside-down in the diagnosis of lung cancer,
7 the leading cause of cancer death. If anyone
8 does not believe in the benefit of finding lung
9 cancer as surgically curable disease more than
10 80 percent rather than 15 percent time --
11 That's the national average you were talking
12 about a second ago; right?

13 A. Yes.

14 Q. Please talk to my patients who have had
15 their Stage 1-A lung tumors resected and are
16 alive and well.

17 Now, my question to you is this, Doctor: Is
18 that your experience diagnosing and early detecting
19 lung cancer in the State of West Virginia that it
20 turns the numbers upside-down?

21 A. Yes.

22 MR. GRUENLOH: Gina, could you please show the
23 defendants chart again, the not safe?

24 BY MR. GRUENLOH:

1 Q. All right. Again, Doctor, I'm showing you
2 one of the charts that I think it was Mr. Woodside
3 used in his opening statements. And the final point
4 on there reads, "Spiral CT not effective." And let
5 me ask you, do you believe that spiral CTs are not
6 effective?

7 A. We use it every day, and it works.

8 Q. Okay.

9 MR. GRUENLOH: Could we see that --
10 BY MR. GRUENLOH:

11 Q. Doctor, I'm showing you another article you
12 reviewed in this case. This article is entitled
13 "Screening for Lung Cancer" by Dr. Ollie S.
14 Meittinen.

15 Let's see where that is published, Gina.

16 It's published in Lung Cancer, and what's the
17 date of that article? I believe it was recent.
18 There we are, in May of 2000.

19 First of all, Doctor, have you read this
20 article?

21 A. Yes.

22 Q. All right. Is this the type of article
23 that a physician such as yourself who specializes in
24 the early detection of lung cancer would rely upon?

1 A. Yes.

2 Q. Have you, in fact, relied upon this article
3 to form the basis of your opinions in this case?

4 A. Yes.

5 Q. All right. Let's see the part we have
6 blown up. It reads:

7 Because screening for lung cancer
8 advances the stage at which the disease is
9 typically diagnosed, and --

10 I want to stop there. What does that mean?

11 A. That means by ability to screening, you are
12 picking up cancer earlier than you would otherwise.

13 Q. Okay. And Dr. Meittinen, by the way, is
14 talking about low dose spiral CT scans in this
15 article; is that correct?

16 A. That's correct.

17 Q. And because evidence clearly shows that
18 earlier stage intervention leads to
19 substantially higher rates of survival --

20 Let's stop there. What does Dr. Meittinen mean
21 by that?

22 A. That means, if you pick it up early, and
23 you intervene or treat it or surgically take it out,
24 you have a maximum chance of saving lives in

1 patients.

2 Q. All right.

3 There is no doubt, no doubt that
4 screening for lung cancer is an effective means
5 to prevent deaths from this otherwise highly
6 fatal disease.

7 Again, Doctor, do you believe that CT scans are
8 an effective means of preventing death from lung
9 cancer?

10 A. Yes.

11 MR. GRUENLOH: Gina, let's see the defendants'
12 chart on organization.

13 BY MR. GRUENLOH:

14 Q. Doctor, this is another chart that the
15 defendants use in the opening statements.

16 Is there any way you can blow that up a little
17 bit?

18 This is another chart the defendants use in
19 their opening statements, and I just have a couple
20 of questions on this for you.

21 First of all, it reads "Public Health
22 Recommendations, Medical Monitoring for Healthy
23 Smokers." It says "Organization," and it lists a
24 bunch of organizations. Then it says, "Lung Cancer

1 and COPD," and it has a box to check yes or no
2 whether they have recommended it.

3 And for the purposes of my questions, I'm only
4 going to ask you about the lung cancer boxes. We
5 are not going to talk about COPD now. Let me ask
6 you first, have you seen this chart before today?

7 A. Yes.

8 Q. All right. Have you reviewed the positions
9 of these organizations on the subject of lung cancer
10 screening?

11 A. Yes.

12 Q. All right. Let me ask you, Doctor, is that
13 an accurate chart in your opinion?

14 A. I don't think.

15 Q. Can you explain to me why you don't think
16 it's accurate?

17 A. Well, first of all, these recommendations
18 were based a few years ago when the data was all
19 based on the chest x-ray used for screening of lung
20 cancer.

21 As we know, CT is relatively new test. It came
22 on maybe over the last decade. And there has been
23 lack of long trials because of it's a relatively new
24 test, so nobody has been able to have long survival

1 rate differences proven yet based on CT.

2 So most of the people, they leave this open for
3 lack of long data. And a lot of physicians that I
4 know in the Society for Thoracic Radiology and
5 American College of Physicians, for example, they
6 are of the belief --

7 MR. WOODSIDE: Your Honor, I object. Hearsay.

8 THE COURT: Overruled.

9 MR. WOODSIDE: And speculation.

10 THE COURT: Okay. That's a separate
11 objection?

12 MR. WOODSIDE: Yes, sir.

13 THE COURT: And it's separately overruled.

14 A. For example, I was at the international
15 lung cancer screening conference which we have every
16 year where all the experts in the field come in New
17 York a couple of years ago, and obviously there is a
18 lot of debate.

19 And most of the physicians believe -- they use
20 CT in their practice, and they are convinced that's
21 the best way to detect cancer very early on. And
22 the emphasis now is to design in a hurry to prove by
23 randomized trial to convince this organization that
24 actually it is so; that CT scanning will lead to

1 long-term survival rate benefit in patients.

2 Q. What I want to ask you about this chart,
3 Doctor, is, as a physician who detects lung cancer
4 and diagnoses lung cancer in West Virginia with the
5 use of the low dose spiral CT, does the fact that
6 any of those organizations may or may not have
7 recommended lung cancer screening affect your
8 opinion?

9 A. No.

10 Q. All right. Why is that, sir?

11 A. Well, for several reasons. Number one,
12 when I interact with all those physicians in
13 national meetings, you know, there is a large body
14 of physicians, and you go to attend the seminars and
15 lectures, that's the impression you walk away, that
16 there is not much doubt in everybody's mind that CT
17 scanning is the best way to screen lung cancer.

18 The only thing that's not there is,
19 unfortunately, long randomized trials showing the
20 data that was there before done with chest x-rays.
21 That's because the CT scanning is relatively new.

22 Q. CT -- low dose spiral CT scan costs about
23 three hundred bucks to get done at your university?

24 MR. WOODSIDE: Your Honor, I object and move to

1 strike. If necessary, can we approach the bench on
2 this?

3 THE COURT: Yeah.

4 (At sidebar:)

5 MR. WOODSIDE: Your Honor, I object to this.
6 It's purely subjective that everything related to
7 this case to cost is a subsequent phase to
8 litigation. That's not relevant to this part of the
9 case.

10 MR. GRUENLOH: Your Honor, I withdraw.

11 MR. FURR: The trouble is, the jury has been
12 alerted to this now.

13 THE COURT: What do you want me to do?

14 MR. FURR: We think the door has been opened
15 that we may now be in a position that we need to put
16 on evidence relating to the cost of these figures to
17 the rate at which they would be utilized and lots of
18 other issues that previously have been referred to
19 Phase II. It's something we have to think about.
20 It's highly prejudicial in front of this jury.

21 THE COURT: What I'm going to do now is I'm
22 going to sustain the objection before the jury, and
23 I'm going to tell them that the cost is not a
24 relevant inquiry in this trial. That's what I'm

1 going to do now.

2 MR. KLEIN: I would also request you instruct
3 them that the purpose of the question was not
4 intended to prejudice them, and they should
5 disregard the question.

6 MR. GRUENLOH: Your Honor --

7 THE COURT: Wait. I will be happy to let you
8 do that. The purpose of the question was to --

9 MR. KLEIN: The impact of the question was
10 prejudicial, and they should disregard it.

11 MR. GRUENLOH: I think the defendants can put
12 on evidence that spiral CT scan is such an advanced
13 technology, and I think they are going to imply to
14 this jury that, because of the evidence that they
15 are going to hear, that the fact that it's a very
16 new technology, I think they are going to think that
17 this is a technology that, it's just incredibly
18 expensive, and that's the purpose of the question.
19 And like I said, it was a throw-in, and I can
20 withdraw.

21 MR. FURR: The purpose of the question was to
22 influence the jury of the cost of the spiral CT.

23 MR. GRUENLOH: That's not what I said.

24 THE COURT: There was another way to have

1 approached that particular area without getting into
2 a cost. I'm going to simply say that the question
3 was improper, and the jury is to totally disregard
4 any evidence relating to the cost.

5 I'm not going to use the word "prejudicial" at
6 this time. But everybody can have their objections
7 preserved, and as to what happens in regard to how
8 this evolves in further presentation will have to be
9 worked out.

10 MR. FURR: I understand that.

11 (In open court:)

12 THE COURT: All right. Ladies and gentlemen,
13 the issue relating to the cost of, in this case, a
14 spiral CT is not a relevant inquiry in this case.
15 The question was improper. The objection will be
16 sustained, and you will be instructed to disregard
17 any evidence whatsoever relating to the cost of this
18 particular procedure.

19 MR. GRUENLOH: Gina, could you please put up
20 the chart that has the organizations on it again?
21 Thank you.

22 BY MR. GRUENLOH:

23 Q. Doctor, this is the chart that we looked at
24 just a moment ago that was one of the defendants'

1 demonstratives in their opening statements. Just
2 one last question before we move on.

3 Is it your opinion that the recommendations of
4 some of these organizations that there may not be
5 enough evidence to recommend CT screening at this
6 time, is it your opinion that that is based upon
7 x-rays and not CT scans?

8 A. Yes.

9 Q. Doctor, are you familiar with a policy on
10 lung cancer screening in Japan?

11 A. Yes.

12 Q. All right. Can you please describe what's
13 going on in Japan with low-dose CT scans and lung
14 cancer screening?

15 A. Yes. They have a very aggressive lung
16 cancer screening program on a national basis because
17 of the very high incidence of smoking. They have
18 mobile CT scanners, so they implement the screening
19 program using spiral CT.

20 Over the years, they have done it, and they
21 have published very good results, including
22 improvement in the survival rates doing those spiral
23 CTs.

24 Q. So what we are asking for here, the

1 screening using low-dose CT scans for lung cancer,
2 is already being done in Japan; right?

3 A. Yes.

4 Q. And that's been going on for, what, about
5 fifteen years?

6 A. Yes.

7 Q. Let's talk about the most recent study
8 that's still in progress. The jury has already
9 heard a lot about Dr. Henschke, and her study is
10 called the ELCAP project. Are you familiar with
11 that project?

12 A. Yes.

13 Q. All right. You said you've actually, in
14 fact, met with Dr. Henschke, haven't you?

15 A. Yes.

16 MR. GRUENLOH: Will you please put up the
17 Henschke study? Not the table, the actual article,
18 the Henschke study.

19 Wrong one. There we are.

20 BY MR. GRUENLOH:

21 Q. Doctor, this is an article entitled "Early
22 Lung Cancer Action Project, A Summary of the
23 Findings on Baseline Screening." And it's authored
24 by, among others, Dr. Claudia Henschke.

1 Gina, could you put go down to the bottom and
2 we can see the date down there.

3 It appeared in The Oncologist in 2001.

4 First of all, Doctor, have you read this
5 article?

6 A. Yes.

7 Q. Is this the type of article that physicians
8 such as yourself who specialize in the early
9 detection of lung cancer would rely upon as the
10 basis of your opinions?

11 A. Yes.

12 Q. And have you, in fact, relied upon this
13 article to form the basis of your opinion in this
14 case?

15 A. Yes.

16 Q. All right. Let's look at the article. It
17 says, "baseline results." That means what they
18 found; right?

19 A. Yes.

20 Q. On low-dose CT at baseline compared to
21 chest radiography, NCN --
22 What is NCN?

23 A. Noncalcified nodules.

24 Q. Is that a tumor?

1 A. Yes.

2 Q. Were detected three times as commonly, 23
3 percent versus 7 percent, malignancies four
4 times as commonly, 2.7 percent versus 0.7
5 percent, and Stage 1 malignancies six times as
6 commonly, 2.3 percent versus 0.4 percent.

7 Then it reads:

8 Of the 27 CT-detected cancers, 96 percent
9 were resectable, 85 percent were Stage 1, and
10 83 percent were not seen on chest radiography.

11 Can you explain the significance of that
12 statement, sir?

13 A. What that means is that, if you use
14 low-dose CT scanning for screening, that, compared
15 to the conventional way of diagnosing with chest
16 x-ray, you will pick up the nodules three times as
17 often, you will pick up cancer four times as often,
18 and most of the cancers that you will pick up will
19 be early stage, when it's still curable.

20 Q. Okay. And just so we all understand,
21 Doctor, what Dr. Henschke did was not a long-term
22 randomized clinical trial, was it?

23 A. No.

24 Q. Okay. Can you explain what, in fact, she

1 did?

2 A. The CT screening program in New York City
3 where they looked at asymptomatic smokers where they
4 performed CT scan on as many as close to one
5 thousand smokers with a history of smoking, and they
6 found in those patients, like you mentioned, there
7 were that many cancers that they found in
8 asymptomatic patients.

9 Q. Okay. Let's continue.

10 Following the ELCAP recommendations,
11 biopsies were performed on 28 of the 233
12 subjects with NCN. 27 had a malignant and one
13 a benign NCN. Another three individuals
14 underwent biopsy outside of the ELCAP
15 recommendations. All had benign NCNs. No one
16 had a thoracotomy for a benign nodule.

17 My question to you is this, Doctor. In the
18 context of what we have been talking about, false
19 positives, how does that bear upon that issue?

20 A. Basically in their study, using CT
21 screening in a thousand asymptomatic smoking
22 subjects, they did not have a false positive. If
23 you look at the surgery, they only had one false
24 positive for biopsy.

1 Q. Let's go down to the conclusion. The
2 conclusion reads:

3 Baseline CT screening for lung cancer
4 provides for detecting the disease at earlier
5 and presumably more commonly curable stages in
6 a cost-effective manner.

7 MR. WOODSIDE: Your Honor, I object. May we
8 approach the bench begin?

9 MR. FURR: Turn that off.

10 (At sidebar:)

11 MR. GRUENLOH: This demonstrative has already
12 been shown to the jury once before. I understand
13 the objection in light of the questions.

14 MR. WOODSIDE: I haven't made it yet.

15 MR. GRUENLOH: Because I know the objection you
16 are going to make.

17 THE COURT: Well, you may be; I am not. Let me
18 hear the objection. It makes it a little easier to
19 rule.

20 MR. WOODSIDE: My objection, he referred to to
21 the cost, it being a cost-effective tool. And
22 that's exactly the same thing he did a few minutes
23 ago, and it's even more egregious now because we
24 just went through this ten minutes ago, and I

1 object. It's prejudicial, and it's not in this part
2 of case.

3 MR. GRUENLOH: As I said, I understand the
4 objection. But we gave them the demonstrative
5 forty-eight hours in advance. We received no
6 objection on the demonstrative. The purpose of the
7 question has nothing to do with whether or not the
8 test is cost-effective.

9 MR. WOODSIDE: Your Honor, here is the
10 question. It might not be so bad in and of itself,
11 but coupled with the question he just asked before
12 about the three hundred dollars cost, it clearly
13 becomes prejudicial and is clearly not in this case.

14 To have let it slip by one time would be one
15 thing. But in light of what he did a few minutes
16 ago, it's objectionable and entirely inappropriate,
17 in the wrong phase of the case, and prejudicial.

18 MR. GRUENLOH: Your Honor, if you would like, I
19 could withdraw the question and ask it a different
20 way. The purpose of the question has nothing to do
21 with that.

22 THE COURT: I understand. And I'm not
23 ascribing any mal motive. What you are really
24 looking for was a zipper to the first part of the

1 article.
2 MR. GRUENLOH: That's right.
3 THE COURT: But it clearly touches again on the
4 issues of cost.
5 Now, I will once again instruct the jury, if
6 you want me to, in the same manner as I did before.
7 MR. FURR: We do, including that the question
8 was inappropriate.
9 THE COURT: Well, improper.
10 MR. GRUENLOH: Your Honor, can I respond to
11 that? I didn't pose a question.
12 MR. FURR: Well, you read --
13 THE COURT: Well, I'm going to use the term any
14 reference to cost again is not a proper inquiry.
15 MR. GRUENLOH: I understand.
16 THE COURT: And they will be instructed to
17 disregard any reference or mention of cost or cost-
18 effective.
19 MR. KLEIN: May I just have a moment.
20 MR. GRUENLOH: If I could --
21 MR. KLEIN: Excuse me.
22 THE COURT: Go ahead.
23 MR. GRUENLOH: One solution, I would like to
24 ask the question about the first part of this, and I

1 I could have our technical people redact that in
2 five seconds. Or I have the article with me, and I
3 can just ask him from that.

4 THE COURT: Well, if you want to, go ahead and
5 just get this out of there.

6 MR. GRUENLOH: Okay, I will do that.

7 THE COURT: I don't know, can your fancy
8 machine get that?

9 MR. GRUENLOH: Do that pretty quick.

10 THE COURT: Get it out of there, and I can -- I
11 will still instruct the jury.

12 MR. GRUENLOH: All right.

13 (In open court:)

14 THE COURT: That's all right. I don't want to
15 interrupt you.

16 Ladies and gentlemen, again, I will instruct
17 you that matters or issues or any reference to cost
18 of any procedure is not a relevant inquiry in this
19 proceeding, and any reference to cost or cost-
20 effectiveness is not an appropriate inquiry. It's
21 not a proper subject for your concern, and you will
22 be instructed to disregard any reference to either
23 cost or cost-effectiveness. All right.

24 MR. GRUENLOH: Gina -- Your Honor, would you

1 like to see it before we put it up again?

2 THE COURT: I will take your word for it.

3 BY MR. GRUENLOH:

4 Q. Again, Doctor, this is the Claudia Henschke
5 article we were just talking about. Let me read the
6 conclusion you to again:

7 Baseline CT screening for lung cancer
8 provides for detecting the disease at earlier
9 and presumably more commonly curable stages.

10 My question for you is this, Doctor: As a
11 physician who has already been using low dose spiral
12 CT scans in the State of West Virginia to detect
13 lung cancer at an earlier stages, is that your
14 experience as well?

15 A. Yes.

16 MR. GRUENLOH: Thank you, Dr. Gupta. The
17 defendants are going to ask you some questions.

18 THE COURT: All right. Why don't -- we may
19 have to break up your cross-examination,
20 Mr. Woodside. Is that going to bother you?

21 MR. WOODSIDE: No, sir.

22 THE COURT: All right. Why don't you start
23 cross-examination, and then, when we come to a point
24 where you are getting on to another subject, I would

1 say around 10:15, then we might interrupt.

2 MR. WOODSIDE: Good morning, ladies and
3 gentlemen.

4 Your Honor, Travis Fliehman of our office will
5 be assisting us.

6 THE COURT: All right. That will be fine.

7 MR. WOODSIDE: Mr. Fliehman is a member of the
8 bar of Ohio as well as West Virginia.

9 THE COURT: That's fine.

10 -- -- --

11 CROSS-EXAMINATION

12 BY MR. WOODSIDE:

13 Q. Good morning, Dr. Gupta.

14 A. Good morning.

15 Q. You will recall we met about a year or so
16 ago when your deposition was taken in this case over
17 in Morgantown?

18 A. Yes, sir.

19 Q. I'm going to ask you a number of questions
20 this morning. Sometimes I will skip around in order
21 to ask you questions that relate specifically to
22 what you said, and I will try not to be disjointed.

23 As I understand the situation from the
24 questions Mr. Gruenloh asked you, you are not board

1 certified in the field of radiology; is that
2 correct, sir?

3 A. That's correct.

4 Q. All right. Board certification in general
5 is a process wherein physicians who have completed
6 the requisite training in any given specialty or
7 subspecialty and have completed and fulfilled the
8 appropriate requirements are then eligible to be
9 examined by the American board for that specialty or
10 subspecialty to determine if they are basically
11 qualified to meet their requirements; correct?

12 A. That's correct.

13 Q. Okay. Now, as I understand the situation,
14 sir, you are board certified in the field of nuclear
15 medicine; correct?

16 A. That's correct.

17 Q. In addition to not being board certified in
18 the field of radiology, you are not board eligible
19 in the field of radiology, are you, sir?

20 A. That's correct.

21 Q. And you have not completed a formal
22 radiology training program, have you, sir?

23 A. That's correct.

24 Q. Indeed, sir, you have never been in a

1 formal training program in radiology, either in the
2 United States or in India; correct?
3 A. As a student?
4 Q. As a resident?
5 A. That's correct.
6 Q. All right. And in addition, as I
7 understand the situation, you are the director of
8 the division of nuclear medicine at the medical
9 school at West Virginia University?
10 A. That's correct.
11 Q. And that is within the Department of
12 Radiology; correct?
13 A. That's correct.
14 Q. You are familiar with the concept of staff
15 privileges; are you not?
16 A. Yes.
17 Q. And indeed, at -- is it Ruby Medical Center
18 at West Virginia University; is that the name of the
19 medical center, Ruby?
20 A. Ruby Memorial Hospital.
21 Q. And that's the medical center at West
22 Virginia University in Morgantown?
23 A. That's correct.
24 Q. And there are in the Department of

1 Radiology many well qualified, fully trained and
2 board certified radiologists; correct?
3 A. That's correct.
4 Q. Okay. And at your hospital, you do not
5 yourself read and formally sign off and charge for
6 the readings of chest x-rays; correct?
7 A. That's correct.
8 Q. And the same would also be true for CT
9 scans; correct?
10 A. Correct.
11 Q. Now, just so we are clear, you are also not
12 trained and board certified in the area of
13 epidemiology?
14 A. Correct.
15 Q. The same would also be true for
16 biostatistics?
17 A. Correct.
18 Q. You mentioned, I believe, in your direct
19 examination, the fact that, at West Virginia
20 University Medical Center, at Ruby, there was a team
21 of individuals who I believe made up the
22 comprehensive cancer treatment center?
23 A. Comprehensive lung cancer program.
24 Q. Comprehensive lung cancer program.

1 In that program, there are medical oncologists;
2 correct?
3 A. Correct.
4 Q. And you are not formally trained and
5 certified in the field of medical oncology; correct?
6 A. Correct.
7 Q. There are also general and thoracic
8 surgeons who are members of the comprehensive lung
9 care program; correct?
10 A. Correct.
11 Q. And if my understanding of the situation is
12 correct, during the first part of your training
13 after medical school, you were in surgical residency
14 program; correct?
15 A. Correct.
16 Q. You did not complete the surgical residency
17 program; correct?
18 A. Correct.
19 Q. And just so we are clear, you are not fully
20 trained and board certified in the fields of either
21 general surgery or thoracic surgery; correct?
22 A. Correct.
23 Q. You are not trained in public health?
24 A. Correct.

1 Q. With regard to medical monitoring or
2 screening, you have never had any formal training in
3 the performance of medical monitoring or screening
4 studies; correct?

5 A. Correct.

6 Q. And you have never performed a medical
7 monitoring study with real human subjects involved,
8 have you, sir?

9 A. Correct.

10 Q. All right. At Ruby Memorial Hospital in
11 Morgantown, you have a practice in nuclear medicine;
12 correct?

13 A. Correct.

14 Q. And that is primarily a referral practice;
15 correct?

16 A. Correct.

17 Q. You are not what is called a primary care
18 physician; correct?

19 A. Correct.

20 Q. And you are not the individual physician
21 who generally orders spiral CT tests; correct?

22 A. Correct.

23 Q. And indeed, you are not the individual
24 physician who actually requests or makes the

1 referral of patients to the nuclear medicine
2 service; correct?

3 A. Correct.

4 Q. Now, generally speaking, sir, the patients
5 that you have seen over the years who ultimately
6 come to be diagnosed with lung cancer are
7 individuals with some sort of signs or symptoms of a
8 chest condition who are referred to you for workup
9 of that condition; correct?

10 A. Most, but not all.

11 Q. The overwhelming majority; correct?

12 A. Yes.

13 Q. All right. Now, I don't believe that I
14 need to put the plaintiffs' demonstrative exhibits
15 back up on the screen. They provided me with copies
16 and I just have a number of questions that I want to
17 ask on some of them to you about. And they will be
18 very direct and straightforward and, if we need to
19 put the big demonstratives up, you or I can request
20 it. Fair enough?

21 A. Sure.

22 Q. Now, you showed a demonstrative exhibit in
23 which there was a young woman who was receiving a
24 chest x-ray; correct?

1 A. Correct.

2 Q. Okay. And you understand that that chest
3 x-ray is not part of the plaintiffs screening or
4 medical monitoring plan in this case?

5 A. Correct.

6 Q. All right. You will recall that --

7 MR. WOODSIDE: Gina, could we put this one back
8 up?

9 BY MR. WOODSIDE:

10 Q. Dr. Gupta, I have replaced on the screen
11 one of the plaintiffs' demonstrative exhibits that
12 was used in your direct examination, and I would
13 like to refer to that and ask you a number of
14 follow-up questions.

15 Can you see that okay?

16 A. Correct.

17 Q. All right. At the top there is a chest
18 x-ray which you indicated was read as normal;
19 correct?

20 A. Correct.

21 Q. Now, first of all, you are not the one that
22 did the formal reading of that as a radiologist and
23 determined that it was normal; correct?

24 A. Correct.

1 Q. And indeed, I suspect that, at the time
2 that chest x-ray was ordered, you had not become
3 involved in that patient's care and treatment;
4 correct?

5 A. Correct.

6 Q. And was this actually a patient of yours?

7 A. Yes.

8 Q. And when was that, sir?

9 A. When the patient had a PET scan in our
10 center.

11 Q. Okay. So what happened was, first, the
12 patient had a chest x-ray which was read and normal;
13 correct?

14 A. Correct.

15 Q. And then the patient had a CT scan
16 thereafter?

17 A. Correct.

18 Q. And you were not the one who ordered that
19 CT scan, were you, sir?

20 A. Correct.

21 Q. Now, as I understand your testimony, you
22 indicated that, on the CT scan, a nodule was found,
23 and I believe, sir, that you indicated that this
24 particular white opacity was the nodule; correct?

1 A. Correct.
2 Q. Okay. Now, this is not a trick question.
3 I sometimes have a little trouble hearing in the
4 courtroom. I think I heard what you said and I'm
5 going to repeat it and then follow up with you. I
6 think what you said was this was a solitary
7 pulmonary nodule; correct?
8 A. Correct.
9 Q. Solitary meaning single?
10 A. Correct.
11 Q. Pulmonary meaning in the lungs?
12 A. Correct.
13 Q. Nodule meaning that's what you call this
14 size of white spot; correct?
15 A. Correct.
16 Q. Now, a nodule, itself, may or may not be a
17 tumor; correct?
18 A. Correct.
19 Q. Okay. It could be a number of other
20 conditions; correct?
21 A. Correct.
22 Q. Now, I think you indicated that, in order
23 to determine whether this nodule is or is not
24 cancerous, that there have to be a workup; correct?

1 A. Correct.

2 Q. And in the world of medicine, the words
3 "workup" mean a follow-up diagnostic procedure or
4 test; correct?

5 A. Correct.

6 Q. And just so we are clear, when this CT scan
7 was taken, do I understand that thereafter -- was
8 this a man or a woman? It doesn't make a
9 difference.

10 A. I don't remember.

11 Q. I don't know whether to refer to it as he
12 or she. I will refer to it as the patient.

13 It was after the x-ray, after the CT, then the
14 patient was referred to you for PET scan; correct?

15 A. Correct.

16 Q. Now, just so we are clear, based upon a CT
17 scan, finding a single pulmonary nodule like that,
18 you would not tell this patient that he or she did
19 have cancer or did not have cancer, would you?

20 A. I would say 40 to 50 percent chance of
21 cancer.

22 Q. But just so we are clear, I'm going to ask
23 you a very direct question. You would not say to
24 that patient you have cancer, would you?

1 A. I would say 40 to 50 percent chance of
2 cancer.

3 MR. WOODSIDE: Your Honor, could I request he
4 answer the question yes or no. I will follow up,
5 sir.

6 THE COURT: Are you able to answer that
7 question either agreeing or disagreeing, doctor?

8 THE WITNESS: I think it's the wrong question.
9 (Laughter)

10 THE COURT: Well, unfortunately -- I mean, if
11 you want to switch roles.

12 THE WITNESS: It's a wrong question to answer,
13 because usually we don't say --

14 THE COURT: Is it possible to give a yes or no
15 answer to the question?

16 THE WITNESS: No. That's what I meant.

17 MR. WOODSIDE: All right.

18 BY MR. WOODSIDE:

19 Q. I don't disagree with that. Let me make
20 sure I understand something.

21 It is not possible to tell the patient --
22 strike that.

23 And I want to ask a series of questions so you
24 can fully explain.

1 Based upon the finding on low-dose CT of a
2 solitary pulmonary nodule such as the one shown on
3 the screen, it is not possible to tell the patient
4 yes, you do have cancer, or no, you do not have
5 cancer; correct?
6 A. What basically you have --
7 Q. Excuse me, Your Honor --
8 A. Can you reframe the question, please? Or
9 restate it, I'm sorry.
10 THE COURT: Well, the question -- you cannot
11 answer the question as presented?
12 THE WITNESS: It would be tough, based on this
13 alone, to say whether a patient has cancer or not;
14 that is correct.
15 BY MR. WOODSIDE:
16 Q. And therefore, it's for that reason that
17 you would want some follow-up diagnostic work done;
18 correct?
19 A. Correct.
20 Q. Okay.
21 MR. WOODSIDE: Ms. Gina, you can take that
22 off. Thank you.
23 BY MR. WOODSIDE:
24 Q. I want to skip around to a number of the

1 other demonstratives which were used by the
2 plaintiffs. You will recall -- --

3 MR. WOODSIDE: Ms. Gina, could you put this
4 up. I apologize. This would be the Thomas Petty
5 article.

6 BY MR. WOODSIDE:

7 Q. Now, sir, you recall that Mr. Gruenloh
8 asked you questions about this particular article
9 that appeared in Chest; correct?

10 A. Yes.

11 Q. Okay. And this appeared as an editorial;
12 correct?

13 A. Correct.

14 Q. Okay. Now, I believe that you read
15 portions of the right-hand side which said -- and I
16 will start in the middle to make it easy. It starts
17 out talking about screening. It says:

18 We need the same for lung cancer.

19 Do you recall that? Do you see that?

20 A. Yes.

21 Q. A very recent study offers a pragmatic
22 approach to lung cancer screening via high-
23 resolution CT scanning.

24 Did I read that correctly?

1 A. That's correct.

2 Q. And sir, do you understand that that's not
3 the plaintiffs' proposed plan in this case because
4 that says high resolution CT scanning, and we are
5 not talking about that, are we, sir?

6 A. No. We are talking about low-dose CT.

7 Q. Thank you very much.

8 MR. WOODSIDE: Thank you, Ms. Gina.

9 BY MR. WOODSIDE:

10 Q. Now, on the slides or demonstratives which
11 Mr. Gruenloh put up, there was one talking about the
12 stages of lung cancer. Do you recall that, sir?

13 A. Correct.

14 Q. Now, it may well be that I need to put that
15 slide up again. I won't know until I ask you a
16 couple of questions.

17 First of all, do I understand you to be of the
18 opinion that early diagnosis is a goal to be
19 achieved; correct?

20 A. Correct.

21 Q. Now, the situation is that, over a period
22 of time, tumors grow by the phenomenon of doubling;
23 correct?

24 A. Correct.

1 Q. And what happens is you start out with a
2 single cell, and then that splits by a process known
3 as mitosis into two cells; correct?
4 A. Correct.
5 Q. And then those two cells split into four
6 cells; correct?
7 A. Correct.
8 Q. And those four cells then split into eight
9 cells; correct?
10 A. Correct.
11 Q. Now, that process is referred to as
12 doubling; correct?
13 A. Correct.
14 Q. And the time it takes for each one of those
15 splittings to occur is referred to as the doubling
16 time; correct?
17 A. Correct.
18 Q. And the doubling time for cancer in the
19 lung can differ from tumor to tumor; correct?
20 A. It does differ.
21 Q. Very good. And can you tell us, for
22 instance, for adenocarcinoma of the lung, what the
23 doubling time is?
24 A. The doubling time can range from anywhere

1 from aggressive cancers, thirty days to as high as
2 150 days.

3 Q. Now, because you can have some cancers
4 which are aggressive and some which are not
5 aggressive, it's true, is it not, that the biology
6 of the given tumor cell can affect how long it takes
7 for the cells to double and grow?

8 A. Correct.

9 Q. All right. Now, I believe --

10 MR. WOODSIDE: Ms. Gina, can we put this up? I
11 appreciate your help.

12 BY MR. WOODSIDE:

13 Q. Now, just so we are clear, we start out
14 with a single cell, which is .001 centimeters;
15 correct?

16 A. Correct.

17 Q. And this, of course, is much, much, much,
18 much, much larger than .001 centimeters; correct?

19 A. Correct.

20 Q. And if we took a pencil or pen and just
21 made a dot on a page, it would be probably be much,
22 much, much, much larger than .001 centimeters;
23 correct?

24 A. Correct.

1 Q. Now, so on this chart, for instance, when
2 we get down here to a nodule one cubic centimeter,
3 and then we go over here on the right side to the --
4 where we are showing how large that would be, that's
5 actually much larger than one cubic centimeter,
6 isn't it?

7 A. Yes. It's a diagrammatic representation.

8 Q. This is supposed to be diagrammatic and
9 showing your point, as opposed to being
10 scientifically and technically accurate; correct?

11 A. It's not accurate in terms of dimensions,
12 but it's still scientifically sound.

13 Q. What was the last word?

14 A. The size probably does not reflect the
15 exact size in centimeters, but the concept is
16 scientific.

17 Q. Now, do you know how long it takes for
18 there to be ten doublings?

19 A. It depends on the aggressiveness of the
20 tumor.

21 Q. It would probably be measured in years;
22 correct?

23 A. You can have doubling times as small as 20
24 days, 25 days.

1 Q. Or as long as four hundred days; correct?
2 A. Correct.
3 Q. It's true, is it not -- strike that.
4 I believe you indicated that a nodule that's
5 one cubic centimeter would be -- that's when they
6 are first visible on chest x-ray; correct?
7 A. Correct.
8 Q. And I believe you indicated smaller ones
9 would be -- excuse me, the CT scan would pick them
10 up a little earlier; correct?
11 A. Much earlier.
12 Q. Now, a nodule -- and I'm using this to
13 demonstrate a concept -- that's one centimeter --
14 one cubic centimeter that's had 30 doublings would
15 have been present for years by the time it's finally
16 picked up; correct? Between the time it went from a
17 single cell to this nodule, it would have been there
18 for years, correct, growing?
19 A. It could have been, but an aggressive tumor
20 may not have been there that long.
21 Q. So it may have been there for years; it may
22 not have been there for years; correct?
23 A. Correct.
24 Q. Some tumors which are not aggressive can be

1 very slow growing; correct?
2 A. Correct.
3 Q. And those can be referred to as indolent
4 tumors; correct?
5 A. Correct.
6 Q. Now?
7 MR. WOODSIDE: Your Honor, I'm not sure what
8 time you wanted to take a break.
9 THE COURT: Are you at a point now where you
10 are going to leave this particular area?
11 MR. WOODSIDE: It would be better for me to
12 break right now.
13 THE COURT: Is this a convenient time for you.
14 MR. WOODSIDE: This is a very convenient time.
15 THE COURT: All right. Let's take the morning
16 break now.
17 Doctor, you can walk around. You don't have
18 to -- but please don't discuss your testimony with
19 anyone because you are still on the witness stand;
20 all right, sir?
21 THE WITNESS: All right.
22 (A recess is taken.)
23 (In open court with a jury present.)
24 THE COURT: All right. Be seated, please.

1 All right. Mr. Woodside?

2 MR. WOODSIDE: Thank you, Your Honor.

3 BY MR. WOODSIDE:

4 Q. Dr. Gupta, you will recall that there was
5 some reference in your direct examination to this
6 chart of public health recommendations. It's the
7 listing of all the organizations.

8 A. Yes.

9 Q. Okay. I'm going to come back to that in a
10 few minutes, but I want to ask you about something
11 that you said when you were testifying about that so
12 that I don't forget.

13 A. Sure.

14 Q. In discussing that chart, did I understand
15 you to say that it was not the standard to screen
16 for lung cancer with chest x-rays?

17 A. At this time?

18 Q. Yes.

19 A. Yes.

20 Q. Okay. And actually that has been known for
21 a number of years; correct?

22 A. Correct.

23 Q. Now, before I pass on to another area, I
24 just want to conclude one of the areas that we had

1 been discussing. And I think that you said what I'm
2 going to ask you about in so many words, but I
3 didn't phrase my question as articulately as I
4 should.

5 It is not the standard of care practiced by
6 physicians to diagnose lung cancer based on a single
7 low-dose CT finding; correct? By the way, there
8 will be a follow-up question here in a minute.

9 Is that correct?

10 Would you like me to tell you where I am going
11 so you understand?

12 A. I --

13 Q. Let me withdraw the question.

14 I'm first going to ask you that question, and
15 then I'm going to ask you if the way you do a
16 standard of care requires a further diagnostic
17 standard, so forth. It's a two-part question. Do
18 you understand where I'm going?

19 A. I was just going to say that the standard
20 of --

21 Q. Wait, now. In West Virginia, it is not the
22 standard of care practiced by physicians to
23 definitively diagnose cancer of the lung based on a
24 single low-dose CT finding; correct?

1 A. Correct.

2 Q. The standard of care requires that,
3 thereafter, there be a full and complete workup with
4 the appropriate modalities as determined by the
5 physicians in order to come to a diagnosis; is that
6 a fair statement?

7 A. Correct.

8 Q. Okay, thank you.

9 In your practice of nuclear medicine and in
10 preparing to serve as an expert witness in this
11 case, you have had occasion to review hundreds of
12 articles relating to screening and matters such as
13 that; correct?

14 A. Correct.

15 Q. And indeed, you have shown to the ladies
16 and gentlemen of the jury some of those articles
17 which you have reviewed; correct?

18 A. Correct.

19 Q. Now --

20 MR. WOODSIDE: Your Honor, may I approach the
21 bench and the witness?

22 THE COURT: Yes.

23 BY MR. WOODSIDE:

24 Q. Now, Doctor, I have handed you what has

1 been marked Exhibit No. BWB 18663. I would advise
2 you that that's an article entitled "Correlation of
3 Tumor Size and Survival in Patients with Stage 1A
4 Non-small Cell Lung Cancer"; correct?

5 A. Correct.

6 MR. WOODSIDE: Jason, could you bring that up,
7 please? And could we show the title, please?

8 BY MR. WOODSIDE:

9 Q. Now, Doctor, this is an article which deals
10 with the correlation of tumor size and survival in
11 patients with Stage 1A non-small cell lung cancer;
12 correct?

13 A. Correct.

14 Q. And you have previously seen this article;
15 have you not, sir?

16 A. Correct.

17 Q. And this is offered by a number of
18 individuals, including Edward F. Patz, Jr., M.D;
19 correct?

20 A. Correct.

21 MR. WOODSIDE: And would you show the next --

22 BY MR. WOODSIDE:

23 Q. And this was published in Chest in the year
24 2000; correct?

1 A. Correct.
2 Q. And that is a prestigious journal which you
3 yourself review?
4 A. Correct.
5 Q. And this deals with clinical
6 investigations; correct?
7 A. Correct.
8 Q. Can we go to the next page, please?
9 Now, before you blow it up, Jason, this is an
10 article in which the authors did research to
11 determine whether or not there was a correlation
12 with tumor size and survival; correct?
13 A. Correct.
14 MR. WOODSIDE: Jason, could you blow up the
15 first highlighted portion?
16 BY MR. WOODSIDE:
17 Q. The authors report:
18 Nevertheless, it remains unclear if
19 detection of small cancers by CT will result in
20 an earlier stage disease and then translate
21 into a statistically significant improvement in
22 lung cancer mortality.
23 Did I read that correctly, sir?
24 A. Correct.

1 MR. WOODSIDE: Will you show the next one,
2 Jason?
3 BY MR. WOODSIDE:
4 Q. In fact, there is some evidence, including
5 the results of the current study --
6 That would be the study Dr. Patz is doing;
7 correct?
8 A. Correct.
9 Q. That suggests that detection of small
10 nodules does not impact on patient survival.
11 Did I read that correctly?
12 A. Correct.
13 MR. WOODSIDE: Next slide?
14 BY MR. WOODSIDE:
15 Q. The data do not demonstrate a statistically
16 significant relationship between small-size
17 lesions and survival.
18 Did I read that correctly?
19 A. Correct.
20 Q. And what they are saying is just because
21 you found it in a smaller size does not mean that
22 your survival is necessarily better; correct?
23 A. Correct.
24 MR. WOODSIDE: If you would go on to the next

1 one, please? I believe there is one more. Can you
2 blow that up. This is the concluding section.
3 BY MR. WOODSIDE:
4 Q. Although we -- the authors -- remain
5 optimistic about improving outcomes in lung
6 cancer, we caution against the routine
7 widespread use of early detection methods until
8 true statistical mortality advantages are
9 demonstrated in the appropriate prospective
10 randomized trials.
11 Did I read that correctly?
12 A. Correct.
13 Q. Thank you.
14 MR. WOODSIDE: You can take that down.
15 BY MR. WOODSIDE:
16 Q. I started to cover something with you
17 before, but didn't have the right portion of my
18 notes before me.
19 THE COURT: Sounds like the bell in a
20 department store.
21 MR. WOODSIDE: Yes, I was thinking the same
22 thing myself.
23 BY MR. WOODSIDE:
24 Q. Let me tell you -- I'm going to ask you

1 some questions, and I just need some examples of
2 something. When you have these pulmonary nodules
3 that we talked about as you can see on the CT, there
4 can be a differential diagnosis; correct?

5 A. Correct.

6 Q. And that means it could be a number of
7 different things, and we have to work it up to see
8 just what it is; right?

9 A. Correct.

10 Q. With regard to the differential diagnosis
11 of solitary pulmonary nodules, one of the things
12 they could be are malignant tumors; correct?

13 A. Correct.

14 Q. They could also be benign tumors; correct?

15 A. Correct.

16 Q. And just so the jury is clear, benign
17 tumors are not malignant and are not nearly as
18 significant as malignant tumors; correct?

19 A. Correct.

20 Q. Then you can also have infectious
21 granulomas; is that correct?

22 A. Correct.

23 Q. And some of those could be tuberculosis,
24 histoplasmosis or coccidioidomycosis; for instance?

- 1 A. Correct.
- 2 Q. You can also have noninfectious granulomas
- 3 such as rheumatoid arthritis, sarcoidosis?
- 4 A. Correct.
- 5 Q. And then you could also have other
- 6 conditions such as abscesses, pneumonia, silicosis?
- 7 A. Correct.
- 8 Q. Okay. Now, normally speaking, when you
- 9 have a benign nodule, which is not malignant or
- 10 cancerous, that will be calcified; correct?
- 11 A. Correct. Most of the times.
- 12 Q. That's right. And not always, but most of
- 13 the time?
- 14 A. Correct.
- 15 Q. All right. For malignant nodules,
- 16 generally, but not always, there will be no
- 17 calcifications; correct?
- 18 A. Correct.
- 19 Q. You can however, have situations such as
- 20 tuberculosis where it could be -- well, normally it
- 21 would be calcified, it could be noncalcified;
- 22 correct?
- 23 A. Correct.
- 24 Q. And that could happen with other

1 conditions. That's just one example; correct?

2 A. Correct.

3 Q. Now, I'm going to ask you a couple of
4 questions, and I will tell you where I am getting
5 the quote from; if I need it, I will get it out.
6 But I'm going to ask you about two statements you
7 made in your report you submitted in this case.

8 The category of nodules less than six
9 millimeters has the highest incidence but the
10 lowest rate of malignancy;
11 Correct?

12 A. Correct.

13 Q. Size of nodules between six and 20
14 millimeters show a higher malignancy rate and
15 is the group most prone to unnecessary surgical
16 resection.

17 Correct?

18 A. Correct.

19 Q. Now, for your benefit, while I have a large
20 notebook, I have lots of pages that are paper
21 clipped, and I don't intend to cover all of this so
22 we will get you out of here in plenty of time.

23 Doctor, you have previously advised me that a
24 screening program is one aimed at detecting very

1 early disease in asymptomatic high-risk population
2 so that there is maximum chances of cure; correct?

3 A. Correct.

4 Q. And such a screening program should not
5 have a significant number of false positives;
6 correct?

7 A. Correct.

8 Q. And also should not have a significant
9 number of false negatives; correct?

10 A. Correct.

11 Q. And with regard to screening programs, you
12 agree, sir, do you not, that the gold standard for a
13 cancer screening test is whether there is a
14 reduction in the likelihood of dying from cancer;
15 correct?

16 A. Correct.

17 Q. I'm going to ask you for some definitions,
18 and I am going to talk conceptually. I don't mean
19 to be inaccurate, but I'm just going to talk --
20 conceptually, I don't mean to be inaccurate, but I'm
21 going to talk conception.

22 A false negative is where the results of the
23 test say you don't have the condition, but you
24 really do; correct?

1 A. Correct.

2 Q. With regard to a false positive, the test
3 says you have a condition when you really do not;
4 correct?

5 A. Correct.

6 Q. And we could agree there is probably some
7 more highly sophisticated technical description of
8 those, sir, but those are the way doctors look at it
9 and discuss it with patients; right?

10 A. Correct.

11 Q. Okay. Now, you have testified, I believe,
12 extensively in your direct examination about lung
13 screening, and in particular you have referred to an
14 article or a series of articles authored by, among
15 others, Dr. Henschke; correct?

16 A. Correct.

17 Q. Now, let me develop some background on
18 this. Dr. Henschke is a radiologist at the Weill
19 Medical College of Cornell University in New York
20 City; correct?

21 A. Correct.

22 Q. And she also has a Ph.D. in mathematics;
23 correct?

24 A. I wasn't aware of that.

1 Q. Well, you know she has a Ph.D.?

2 A. Yes.

3 Q. I've been to her presentations like you. I
4 know she has a Ph.D. in mathematics, but that's not
5 really important.

6 You know she's the director of chest imaging at
7 Cornell?

8 A. Correct.

9 Q. Okay. Now, it is basically her studies
10 that form -- on CT that form the basis for a number
11 of the editorials you presented, as well as a
12 substantial number of other articles in the medical
13 literature dealing with CT; correct?

14 A. Correct.

15 MR. WOODSIDE: May I approach, Your Honor?

16 THE COURT: Yes.

17 BY MR. WOODSIDE:

18 Q. Now, Doctor, --

19 MR. WOODSIDE: And Jason, could you show this
20 for me?

21 BY MR. WOODSIDE:

22 Q. Now, Doctor, you have in front of you the
23 article by Dr. Henschke and others entitled "Early
24 Lung Cancer Action Project: Overall Design And

1 Findings From Baseline Screening."
2 A. Correct.
3 Q. Okay. Now, my next question -- i'm not
4 picking on anybody; okay? This is the first of her
5 publications; correct?
6 A. Correct.
7 Q. And there are a series of other ones which
8 report similar findings, including the one
9 Mr. Gruenloh showed you and put up on the board
10 before.
11 A. Correct.
12 Q. It's the same Dr. Henschke and the same
13 group of studies?
14 A. Correct.
15 Q. This is the first one?
16 A. Correct.
17 Q. Okay. Now --
18 MR. WOODSIDE: Jason, could you highlight the
19 title for me and the authors section? And could you
20 blow this up?
21 BY MR. WOODSIDE:
22 Q. Now, this was authored by Dr. Henschke,
23 Dr. McCauley, Dr. Yanklovitz and a number of others;
24 correct?

1 A. Correct.

2 Q. And these are all well recognized
3 scientists in different disciplines; correct?

4 A. Correct.

5 Q. And if we can go down to the bottom here,
6 The Lancet. And this -- this article was published
7 in The Lancet on July 10, 1999; correct?

8 A. Correct.

9 Q. And then -- and The Lancet is a well known,
10 widely read, esteemed medical journal in the United
11 States and in England; correct?

12 A. Correct.

13 Q. Now, now, I'm going to cover a number of
14 portions of this article. Sometimes I'm going to go
15 back and forth so I know what to blow up for the
16 jury.

17 Now, first of all, we have a summary right
18 here; okay? At the beginning of this paper, like
19 most papers, there is like a little summary or
20 abstract that basically gives you an overview of
21 what's contained in the paper; correct?

22 A. Correct.

23 Q. And that's just the way people do it, and
24 the articles you have have an abstract or summary in

1 the beginning; correct?
2 A. Correct.
3 Q. Now, in this particular article, she
4 reports on the work that they did; correct?
5 A. Correct.
6 Q. All right.
7 MR. WOODSIDE: Now, Jason, could you go down
8 and just highlight the method paragraph right here
9 and blow that up for me.
10 BY MR. WOODSIDE:
11 Q. Now:
12 Methods. ELCAP has enrolled one thousand
13 symptom-free volunteers, aged 60 years or
14 older, with at least ten pack years of
15 cigarette smoking and no previous cancer who
16 were medically fit to undergo thoracic
17 surgery.
18 Did I read that correctly?
19 A. Correct.
20 Q. Now, here is what I want to develop first.
21 There were one thousand symptom-free individuals;
22 correct?
23 A. Correct.
24 Q. They were aged 60 or older?

1 A. Correct.

2 Q. So obviously the average had to be over 60,
3 but the youngest was 60; correct?

4 A. Correct.

5 Q. And they had at least ten pack years of
6 cigarette smoking; correct?

7 A. Correct.

8 MR. WOODSIDE: Now, could we go down, Jason, to
9 the next section?

10 BY MR. WOODSIDE:

11 Q. Now, they found noncalcified nodules in 233
12 participants by low-dose CT at baseline; correct?

13 A. Correct.

14 MR. WOODSIDE: We can back it off, Jason, and
15 go back to the first page.

16 BY MR. WOODSIDE:

17 Q. Now, let me explain to you what I want to
18 do. I want to make sure we understand just what it
19 is that Dr. Henschke and her co-workers did, and I
20 will represent to you that I'm not going to stop
21 halfway through the paper. I'm going to start with
22 what they did early on, and then I'm going to follow
23 through with a carry-over; okay?

24 A. Okay.

1 Q. Or carry through with a follow-up. I'm
2 sorry.

3 MR. WOODSIDE: Now, Jason, could we go to the
4 second page. May we go down under methods and
5 highlight methods and the first alternative.

6 BY MR. WOODSIDE:

7 Q. All right. Start out, in this portion of
8 her paper -- by the way, I will refer to it as her
9 paper because she is the main author, and she's
10 generally acknowledged to be the one with the most
11 authority; correct?

12 A. Correct.

13 Q. And then the first part under methods deal
14 with baseline screening protocol; correct?

15 A. Correct.

16 Q. Now...

17 MR. WOODSIDE: Jason, could you go down two
18 more paragraphs? And I will tell you to highlight
19 it in a minute.

20 At the time of enrollment, information on
21 sex, race, and three determinants of risk, age,
22 smoking habits, and asbestos exposure, were
23 recorded on a questionnaire during an interview
24 with the institution's study coordinator.

1 Did I read that correctly?

2 A. Correct.

3 MR. WOODSIDE: Jason, could you highlight the
4 next sentence? And I will carry over to the next
5 page.

6 BY MR. WOODSIDE:

7 Q. Posterior-anterior and lateral standard
8 chest radiographs were obtained with Insight, Kodak,
9 Rochester, New York, et cetera, film -- and finish
10 that sentence, Jason okay?

11 Now, and helical low-dose CT was obtained with
12 High Speed Advantage CT, et cetera, equipment;
13 right?

14 A. Correct.

15 Q. So with the thousand people that were
16 enrolled in this study under the baseline screening
17 protocol which was the first portion of this
18 article, the thousand patients received -- strike
19 that.

20 Would you call them patients or subjects?

21 A. Subjects.

22 Q. The one thousand subjects first received a
23 posterior-anterior and lateral standard chest x-ray;
24 correct?

1 A. Correct.

2 Q. And just so we are clear, that means each
3 one of them got two x-rays, one front-to-back and
4 one side-to-side; correct?

5 A. Correct.

6 Q. And that's not a part of the plaintiffs'
7 medical monitoring program in this case, is it?

8 A. Correct.

9 Q. In addition, each one thousand individuals
10 got helical low-dose CT; correct?

11 A. Correct.

12 MR. WOODSIDE: Now, Jason, could you go down to
13 the next paragraph. And if you could highlight it,
14 I am going to read the whole thing.

15 BY MR. WOODSIDE:

16 Q. Now, for each of the thousand patients --
17 subjects, excuse me:

18 Each low-dose CT was read separately by two
19 board certified chest radiologists; correct?

20 A. Correct.

21 Q. Then skipping down here:

22 When the two readers could not reach
23 consensus, the case was presented to a third
24 expert reader, and the adjudicated reading

1 became the final one;
2 Correct?
3 A. Correct.
4 Q. So that at least two people and sometimes
5 three read each of the chest x-rays and each of the
6 CTs to determine what the final diagnosis should be
7 based upon that initial screening CT; correct?
8 A. Correct.
9 Q. Now, if between one and six noncalcified
10 nodules were identified on CT, the CT screening
11 result was classified as positive.
12 Correct?
13 A. Correct.
14 Q. So the radiologists looked at each one of
15 the CT -- the low-dose CT scans for each of the one
16 thousand subjects. If they had between one and six
17 noncalcified nodules, as you testified previously
18 what that means, and it was considered to be
19 positive; correct?
20 A. Correct.
21 Q. And that required an individual assessment
22 of each of those CTs; correct?
23 A. Correct.
24 Q. If no noncalcified nodules were identified,

1 the result was classified as negative.
2 Correct?
3 A. Correct.
4 Q. So we have positive if you got one to six;
5 if you got no nodules, it was negative; correct?
6 A. Correct.
7 Q. However there was another class. Instances
8 of more than six noncalcified nodules, diffuse
9 bronchiectasis, ground-glass opacities, or any
10 combination of these features were classified as a
11 diffuse disease.
12 So you could have a third?
13 A. Correct.
14 Q. I will read this:
15 The chest radiograph was read in the same
16 way as of CT, without knowledge of the CT
17 findings, and classified in an identical way.
18 For each nodule identified on the CT, we
19 recorded whether it was present or absent on
20 the chest radiograph;
21 Correct?
22 A. Correct.
23 Q. So what they did was they independently
24 read all the CTs, made individual assessment as to

1 what they showed, and then did the same thing with
2 the chest x-rays and compared the results; correct?

3 A. Correct.

4 MR. WOODSIDE: Now, could we go to the third
5 page? Jason, could we highlight and then blow up
6 this paragraph started over here on the right side.
7 Don't put it up yet. Hold up a second.

8 BY MR. WOODSIDE:

9 Q. I apologize, but I have to skip around a
10 little. You will see where I'm going.

11 Could we blow this word up?

12 This paper has, as with most other scientific
13 papers, also has a section called "Results";
14 correct?

15 A. Correct.

16 Q. And I'm now directing your attention to the
17 results section.

18 A. Correct.

19 MR. WOODSIDE: And, Jason, if you could go back
20 and please blow up this section of the results?

21 BY MR. WOODSIDE:

22 Q. Now, I'm going to read just the second
23 PORTION of this. We can read the first if you like,
24 but --

1 The low-dose CT identified 233
2 individuals as having between one and six
3 noncalcified nodules.

4 Correct?

5 A. Correct.

6 MR. WOODSIDE: You can take it down. I'm going
7 to go back to it, but you can take it off.

8 BY MR. WOODSIDE:

9 Q. To recap on this portion of the paper,
10 there were a thousand individuals that had CT low
11 dose screening CT in the section called baseline
12 screening protocol. Of those one thousand, 233 had
13 positive results; correct?

14 A. Correct.

15 Q. All right. Now, thereafter, there was
16 subsequent additional work done that followed the
17 screening portion of this paper; correct?

18 A. Correct.

19 MR. WOODSIDE: And Jason, could you go back and
20 go to Page 2? I'm sorry, can you go back one page
21 earlier? All right. Now, first, can we start down
22 here and first blow up the lower right-hand corner,
23 Jason, starting with "guidelines"? And first, I
24 want you to highlight this first section up here.

1 Excuse me, just the title.

2 BY MR. WOODSIDE:

3 Q. Then the second portion of this paper
4 reports on the guidelines for diagnostic
5 investigation. Correct?

6 A. Correct.

7 MR. WOODSIDE: And could we blow up the rest --
8 then highlight the rest of the page, and I will read
9 it.

10 BY MR. WOODSIDE:

11 Q. Now, when noncalcified nodules were
12 detected on low-dose CT -- and that's what we talked
13 about before; correct?

14 A. Correct.

15 Q. Those were the 233?

16 A. Correct.

17 Q. A standard-dose, diagnostic CT scan of the
18 chest with high-resolution imaging of the
19 nodule or nodules was recommended for
20 management purposes;

21 Correct?

22 A. Correct.

23 Q. So what happened was, for those who were
24 positive with the low-dose CT, thereafter there was

1 another scan with high resolution -- excuse me,
2 there was a diagnostic CT scan; correct?

3 A. Correct.

4 Q. And a diagnostic CT is not only subsequent
5 to the initial screening CT, but is a little
6 different CT scan.

7 A. Correct.

8 Q. And in addition to the diagnostic CT scan,
9 some of these individuals received high-resolution
10 imaging of the nodule or nodules themselves; correct?

11 A. Correct.

12 Q. Now, if high-resolution CT showed benign
13 calcifications not identified on the low-dose CT in
14 terms of extent or distribution, et cetera, the
15 nodule was classified as benign; correct?

16 A. Correct.

17 Q. So what they did was, with the 233, they
18 then did a supplemental diagnostic CT with high-
19 resolution imaging of the nodules, and they looked
20 at all of those again; correct?

21 A. Correct.

22 Q. And then, if it was benign, they said you
23 are okay, and there will be no further diagnostic
24 workup; correct?

1 A. Correct.
2 Q. Now, if it wasn't determined to be benign,
3 there was additional work done; correct?
4 A. Correct.
5 Q. And one of the first things that was
6 done -- let's go to this section:
7 If these criteria were not met by all of the
8 noncalcified nodules detected in the volunteer --
9 that means it wasn't benign -- the ELCAP protocol --
10 that's Dr. Henschke's protocol; correct?
11 A. Correct.
12 Q -- recommended further investigation
13 according to the size, average of length and width,
14 of the noncalcified nodules; correct?
15 A. Correct.
16 Q. So if it wasn't benign, they had to look at
17 all the diagnostic scan and the high-resolution
18 imaging and, for each one, they had to measure the
19 size of the nodules; correct?
20 A. Correct.
21 Q. Now, I will get to it in a minute, but they
22 divided them into three different sizes; correct?
23 A. Correct.
24 Q. And I will go through each one.

1 The smallest size was five millimeters or less
2 in size; correct?

3 A. Correct.

4 Q. And in this -- I'll read it out loud in a
5 minute, but this explains what they did with those;
6 correct?

7 A. Correct.

8 Q. For those of five millimeters or less in
9 size, the protocol recommended follow-up by high-
10 resolution CT three months later. So, for the
11 smaller ones that they couldn't conclude were
12 benign, you had to have yet another CT three months
13 later; correct?

14 A. Correct.

15 Q. And indeed, if there was no growth, then
16 you had more high-resolution CTs at six months,
17 twelve months and 24 months; correct?

18 A. Correct.

19 Q. So what would happen for each of the
20 individuals who had lesions this size, and each of
21 these times, three months, six months, twelve months
22 and 24 months, there would be high-resolution CTs
23 and each one of them would have to be individually
24 looked at to determine if they were benign or not;

1 correct?
2 A. Correct.
3 Q. And that could be as much as over a
4 two-year period; correct?
5 A. Correct.
6 MR. WOODSIDE: And could we have the next page,
7 please? And Jason, could we blow up the first --
8 yes, that's correct.
9 BY MR. WOODSIDE:
10 Q. Now, the second group were the ones that
11 were a little bit larger. That is, the nodules were
12 a little bit larger; correct?
13 A. Correct.
14 Q. And those were for nodules six to ten
15 millimeters in size; correct?
16 A. Yes.
17 Q. And just TOL recap, they had to
18 individually look at the high-resolution CT to look
19 at how big it was to determine which group you were
20 to be put in; correct?
21 A. Correct.
22 MR. WOODSIDE: And if you would highlight this,
23 Jason?
24 BY MR. WOODSIDE

1 Q. The protocol recommended assessment on an
2 individual basis -- that means they had to look at
3 each one and make an assessment; correct?

4 A. Correct.

5 Q. Of the possibility of undertaking a biopsy
6 by percutaneous transthoracic CT-guided fine
7 needle aspiration or video assisted
8 thoracoscopy biopsy procedures. If no biopsy
9 would be possible, follow-up for growth, as
10 described above, was recommended.
11 Correct?

12 A. Correct.

13 Q. So what they did is, if you were unlike the
14 smaller group, if your nodule, which could or could
15 not be tumor -- by the way, they still hadn't
16 determined whether it was tumor at this stage;
17 correct?

18 A. Correct.

19 Q. On an individual -- on an individual basis,
20 the physicians had to determine whether you should
21 or should not undergo the possibility of a biopsy;
22 correct?

23 A. Correct.

24 Q. And, if it was determined that a biopsy

1 should be performed, then, individually, they had to
2 determine which type of biopsy should be performed;
3 correct?

4 A. Correct.

5 Q. And in doing that, they had to take into
6 consideration the individual condition of the
7 patient, their past medical history and whatnot to
8 see if they are even suitable for a biopsy; correct?

9 A. Correct.

10 Q. Now, let's first talk about a percutaneous
11 transthoracic CT-guided fine-needle aspiration.
12 Now, let's see if you and I can't agree on how to
13 say that a little simpler; okay?

14 A. Okay.

15 Q. What is going to happen is there is going
16 to be a long thin needle that would go through the
17 chest wall, into the chest, itself; it would be --
18 the physician who would be performing this would be
19 guided by yet another CT so you could tell just
20 where to try and put the needle in; correct?

21 A. Correct.

22 Q. And then -- and by the way, then another
23 type was video-assisted thoracoscopic biopsy
24 procedures. And what is this, Doctor?

1 A. This is a surgical procedure where they
2 make a small cut in the chest wall itself, and they
3 are viewing the structures as they are going in, and
4 they are guiding their way.

5 Q. This won't be -- you know, you are not
6 getting set up. Okay. This is to make a point.

7 You know how you indicated to me before that
8 your chart about doubling times was conceptually
9 correct but not necessarily accurate. Do you know
10 what I'm talking about?

11 A. Correct.

12 Q. Okay. I'm going to try and talk about this
13 thoracoscopic biopsy procedure, and I will try to
14 talk conceptually. I may not quite right.

15 You know how -- I think most people know what a
16 laparoscopy is, and you can put it in the abdomen;
17 right?

18 A. Correct.

19 Q. What we are sort of doing is talking about
20 the same sort of procedure.

21 A. Right.

22 Q. You have got a scope, and you make an
23 incision in the chest wall, and then you put the
24 scope in, and then they look through it, and then it

1 would be assisted by a screen where you can see on
2 the television screen, much like we are doing here,
3 what the doctor sees; correct?
4 A. That's correct.
5 Q. Now, who does these procedures?
6 A. A surgeon, thoracic surgeon.
7 Q. A thoracic surgeon, okay.
8 And so before any of these procedures would
9 actually be done, there would have to be a time
10 interval where the patient, or subject, as the case
11 may be, would have to first go -- be referred to a
12 thoracic surgeon. And then a separate session would
13 be set up where they would have to do this; correct?
14 A. Correct.
15 Q. And then, when you do both of these
16 biopsy -- both of these are biopsy procedures;
17 correct?
18 A. Correct.
19 Q. In other words, each time they do it, they
20 try and go in and obtain a little piece of tissue;
21 correct?
22 A. Correct.
23 Q. And that is then sent to the pathology lab
24 for review by yet another specialist; i.e., a

1 pathologist; correct?

2 A. Correct.

3 Q. All right. On the other hand, if no biopsy
4 were possible because, for instance, the patient
5 couldn't undergo it, follow-up would just consist of
6 serial CTs at three, six, nine, twelve and 24
7 months; correct?

8 A. Correct.

9 Q. Now, without going into all of them in
10 detail, you would agree with me, would you not, that
11 there are risks associated with the performance of a
12 percutaneous transthoracic CT-guided fine-needle
13 aspiration; correct?

14 A. Correct.

15 Q. And the same would be true for the video-
16 assisted thoracoscopic biopsy procedure; correct?

17 A. Correct.

18 Q. And at your institution, you would get
19 informed consent forms for these procedures just
20 like you do for any other type of surgical
21 procedure; correct?

22 A. Correct.

23 MR. WOODSIDE: Now, if we could go, Jason, down
24 to the next paragraph, please. And if we could

1 highlight that?
2 BY MR. WOODSIDE:
3 Q. Now, we have talked about the smallest and
4 intermediate size. Let's now talk about lesions
5 which were -- I think this is an eleven; correct?
6 A. Correct.
7 Q. Eleven millimeters or more in size. The
8 plan or the protocol -- I didn't say that right.
9 You see the word "protocol" here?
10 A. Correct.
11 Q. And that's a standard term in medicine;
12 correct?
13 A. Correct.
14 Q. And that is the plan devised by
15 Dr. Henschke and her co-workers which sets forth
16 what is being being done; correct?
17 A. Correct.
18 Q. So, for the larger lesions, the protocol
19 recommended biopsy, according to current standards
20 of care, by fine-needle aspiration -- that's what we
21 discussed before; correct?
22 A. Correct.
23 Q. Video-assisted thoracoscopy -- we discussed
24 that a minute ago?

1 A. Correct.
2 Q. Bronchoscopy, which we did not discuss, but
3 we will in a minute?
4 A. Correct.
5 Q. Or a combination of these methods; correct?
6 A. Correct.
7 Q. Now, bronchoscopy is a procedure whereby
8 you put a long tube through the mouth or nose? How
9 does it go? Through the mouth?
10 A. Right.
11 Q. Down into the lungs and then the physician
12 is able to look through that tube and also, in
13 addition to try to make observations, also can take
14 some tissue or cut a little tissue away to get the
15 biopsy specimen; correct?
16 A. Correct.
17 Q. Now, just like with the other two smaller
18 groups, in order to do this, there is going to have
19 to be an individual evaluation of each patient to
20 determine the size of the nodule on a CT, and then
21 there will be a determination as to which
22 physicians, if any, the patient should be referred
23 to; correct?
24 A. Correct.

1 Q. And then one or more physicians are going
2 to determine whether or not the fine-needle
3 aspiration, thoracoscopy, bronchoscopy or a
4 combination of these methods should be used; right?

5 A. Correct.

6 Q. And those will be individual decisions for
7 each patient or subject based upon the evaluation by
8 the physicians that examine and/or care for he or
9 she; correct?

10 A. Correct.

11 Q. Now, it was only --

12 MR. WOODSIDE: You can take that down.

13 BY MR. WOODSIDE:

14 Q. It was only after all of these steps had
15 been completed that a diagnosis was made in the
16 original 233 positive subjects; correct?

17 A. Correct.

18 Q. Okay. And until these diagnostic steps
19 were taken on an individual basis by various
20 physicians, it was not possible to come to a
21 clinical or pathologic diagnosis as to whether the
22 patients or subjects did or did not have cancer;
23 correct?

24 A. Correct.

1 Q. Now, after this follow-up diagnosis or
2 diagnostic protocol had been followed on an
3 individual basis for the 233 patients or subjects,
4 it turned out that there were 27 that actually had
5 lung cancer; correct?

6 A. Correct.

7 Q. Okay. Now --

8 MR. WOODSIDE: May I use the easel, Your
9 Honor?

10 THE COURT: Sure.

11 BY MR. WOODSIDE:

12 Q. Dr. Gupta, I'm going to use the terminology
13 utilized by Dr. Henschke to summarize in part some
14 of your testimony as to what she and her co-workers
15 did in their study. This is a research study;
16 correct?

17 A. Yes.

18 Q. There were one thousand subjects; correct?

19 A. Correct.

20 Q. Based upon the screening protocol, 233
21 were, in her words, positive; correct?

22 A. Correct.

23 Q. And that was based on the original low-dose
24 screening CT performed by Dr. Henschke and her

1 colleagues at their hospitals and teaching
2 institutions; correct?

3 A. Correct.

4 Q. Now, thereafter, there were diagnostic
5 investigations which were conducted as I have put on
6 the board or the screen and you have testified
7 about; correct?

8 A. Correct.

9 Q. Those diagnostic investigation steps, you
10 understand, are not part of the plan for screening
11 that the plaintiffs propose in this case where they
12 only have one CT, low dose, starting at age 50 and
13 annually thereafter. Do you understand that, sir?

14 A. Correct.

15 Q. Okay.

16 Now, after the diagnostic stage, it turned out
17 that there were 27 verified -- my writing is not
18 very good, I apologize -- cancers; correct?

19 A. I would say "cancers," rather than
20 "tumors".

21 Q. However you would like me to --

22 A. It's fine with me. I would prefer cancer,
23 rather than tumors.

24 Q. That would be fine. Fine. And that's

1 because you have other types of tumors besides
2 cancers?
3 A. Correct.
4 Q. You could have a benign tumor?
5 A. Correct.
6 Q. So what we are really -- let me be
7 medically accurate; okay? These would be malignant
8 tumors or cancer?
9 A. Correct.
10 Q. The difference between these two numbers is
11 206; correct?
12 A. Correct.
13 Q. So there were 206 individuals who, using
14 the screening CT, were listed as being positive that
15 were ultimately not positive for malignant tumors or
16 cancer; correct?
17 A. Correct.
18 Q. Of the original positives, approximately 10
19 percent were actual malignant tumors or cancer;
20 correct?
21 A. Correct.
22 Q. Of the original 233 individuals that were
23 positive after screening CT, approximately 90
24 percent were ultimately determined not to have

1 malignant tumors or cancer; correct?
2 A. Correct.
3 Q. All right.
4 I was too hasty in taking this down. I
5 apologize.
6 The standard of care would prevent you or any
7 other trained physician from telling a patient based
8 upon only the original screening program that the
9 fact that they were positive meant they had cancer;
10 correct?
11 A. Correct.
12 Q. You yourself wouldn't do that, would you?
13 A. No.
14 Q. And you would only tell them they had
15 cancer based upon a follow-up such as was used here
16 or some other follow-up, which might even include
17 PET scan; correct?
18 A. Correct.
19 Q. And one reason you wouldn't tell the
20 patient they had cancer is because of this 233,
21 approximately 90 percent are not going to have
22 cancer; correct?
23 A. Correct.
24 MR. WOODSIDE: Jason, could we show Page 5,

1 please? Jason, could you highlight -- pull up and
2 highlight this -- pull up this full paragraph here,
3 and then I want you to highlight the first
4 sentence.

5 BY MR. WOODSIDE:

6 Q. This is Dr. Henschke again:

7 We have not yet followed up all our
8 participants with malignant disease to
9 determine cure.

10 Correct?

11 A. Correct.

12 Q. And not only did I read it correct, but
13 that's a correct statement; right?

14 A. Correct.

15 Q. They haven't carried the study out long
16 enough to determine whether or not they could
17 determine cure; correct?

18 A. Correct.

19 Q. Now, I think I will have just one more
20 reference to this paper.

21 MR. WOODSIDE: Jason, could you go back to Page
22 NO. 1 for a second? And could you blow up -- don't
23 do anything yet.

24 BY MR. WOODSIDE:

1 Q. You will recall, when I started out my
2 cross-examination on this paper, Dr. Gupta, we had
3 discussed the fact that a summary or abstract is at
4 the front of the paper as a standard practice of
5 major medical journals; correct?

6 MR. WOODSIDE: Jason, could you blow up the
7 interpretation, please? And would you please
8 highlight this sentence right here?

9 BY MR. WOODSIDE:

10 Q. Now, do you still have the article in front
11 of you, Doctor?

12 A. Yes.

13 Q. Although false positive CT results are
14 common, they can be managed with little use of
15 invasive diagnostic procedures.

16 Correct?

17 A. Correct.

18 Q. I want to make sure you and I can agree on
19 what that means. Going back here to the chart I
20 have -- well, I don't know that my writing is good
21 enough to call it a chart. But where I wrote the
22 numbers, you would agree with me, would you not,
23 that Dr. Henschke has said false -- and I'm going to
24 go through the whole sentence, okay, I won't cut you

1 off here -- false positive CT results are common.
2 First, did I read that portion of the sentence
3 correctly?
4 A. Correct.
5 Q. And that refers to the fact that there were
6 233 positives when ultimately only 27 were shown to
7 be malignant tumors, indicating that two hundred or
8 so were falsely positive; correct?
9 A. Correct.
10 Q. And actually the number would be 206?
11 A. Correct.
12 Q. Then she continues on that the common false
13 positive results that you get on your original
14 screening CT can be managed with little use of
15 invasive diagnostic procedures; correct?
16 A. Correct.
17 Q. And what she's talking about is, when you
18 do the screening portion -- strike that.
19 When you do the screening with low-dose helical
20 CT, you get 90 percent false positives which, if you
21 then have a diagnostic follow-up on an individual
22 basis by individual physicians, you can manage those
23 false positives; correct?
24 A. Correct.

1 MR. WOODSIDE: Could we approach the bench for
2 just a minute. It doesn't have to be on the
3 record.

4 (At sidebar:)

5 MR. WOODSIDE: I didn't know what his schedule
6 was. I mean, I'm not sure I will be done by 12:00
7 and I know he wants to leave. I wanted to know what
8 his schedule was so maybe I can conform a little bit
9 what I have got to do to not inconvenience the man.

10 THE COURT: What is his schedule?

11 MR. GRUENLOH: As I understand, he has a
12 meeting back in Morgantown at 4:00, the lung cancer
13 comprehensive program he talked about. I don't have
14 much of a redirect.

15 MR. WOODSIDE: I may be done before lunch.

16 THE COURT: In order to get back there, he
17 should leave here by 2:30.

18 MR. WOODSIDE: I didn't know if I should extend
19 the lunch hour.

20 THE COURT: You can't do that because I have
21 other things. There are other cases going on,
22 believe it or not.

23 MR. WOODSIDE: So we will just follow the
24 regular schedule; okay?

1 THE COURT: Yeah.
2 MR. WOODSIDE: Okay, thank you.
3 (In open court:)
4 MR. WOODSIDE: Jason, can we put up -- may I
5 approach, Your Honor?
6 THE COURT: Sure.
7 BY MR. WOODSIDE:
8 Q. Now, Dr. Gupta, you are familiar with the
9 American Lung Association?
10 A. Correct.
11 MR. WOODSIDE: Blow up for the jury and have
12 displayed here a publication or a statement by the
13 American Lung Association: American Lung
14 Association statement on new CT screening technique
15 for lung cancer, July 29, 1999; okay?
16 Next?
17 ...it is premature for the lung
18 association to endorse screening of all at risk
19 patients with this method.
20 And that method is the CT -- low-dose CT method
21 talked about by Dr. Henschke; correct?
22 A. Correct.
23 MR. WOODSIDE: Jason, there is another -- I
24 think you have got to go down a little.

1 BY MR. WOODSIDE:

2 Q. The technique is not widely available yet
3 and its use requires specialized knowledge:
4 Doctors using the CT technique must be able to
5 distinguish cancerous nodules in the lung from
6 noncancerous nodules. Further, patients and
7 control groups have not yet been followed up to
8 determine whether, in fact, the CT technique
9 will lead to higher cure rates.

10 First, did I read that correctly?

11 A. Correct.

12 Q. And second, when they indicate that
13 patients and control groups have not yet been
14 followed up to determine whether in fact the CT
15 technique will lead to higher cure rates, that's
16 basically parroting or repeating the statement
17 Dr. Henschke said wherein her group had not
18 conducted the appropriate follow-up to determine if
19 there will be higher cure rate; correct?

20 A. Correct.

21 MR. WOODSIDE: Next?

22 BY MR. WOODSIDE:

23 Q. That was authored by Norman H. Edelman,
24 M.D., scientific consultant, American Lung

1 Association.
2 Okay. Thank you.
3 Now, Doctor, you are familiar with the National
4 Cancer Institute. Are you not?
5 A. That's correct.
6 Q. That's a division of the National
7 Institutes of Health, Department of Health and Human
8 Services?
9 A. Yes.
10 Q. And the NCI, as well as -- strike that.
11 NCI stands for National Cancer Institute;
12 correct?
13 A. Correct.
14 Q. And physicians and scientists frequently
15 just refer to it as NCI?
16 A. Correct.
17 Q. And that organization, as well as the
18 American Cancer Society, are probably the two most
19 prominent institutions with regard to cancer
20 research and funding; correct?
21 A. I agree.
22 Q. Okay.
23 MR. WOODSIDE: Now, if we could call up, Jason,
24 RJR 20986? May I approach, Your Honor?

1 THE COURT: Yes.

2 MR. WOODSIDE: Jason, could you blow everything
3 up at the top here?

4 BY MR. WOODSIDE:

5 Q. This is a press release, National Cancer
6 Institute, National Institutes of Health, April 11,
7 2000, press release. And by the way, just so we are
8 clear, the National Institutes of Health is today
9 one of the world's foremost medical research
10 centers; correct?

11 A. Correct.

12 MR. WOODSIDE: Now, go down, Jason? Let's just
13 blow up the first three paragraphs. We will do them
14 one at a time.

15 BY MR. WOODSIDE:

16 Q. Spiral CT scans for lung cancer.

17 Spiral computed tomography, CT or CAT --

18 And by the way, CT or CAT and spiral computed
19 tomography are generally the same thing?

20 A. Correct.

21 Q. Scans are being advertised as a new way to
22 find early lung cancer in smokers and former
23 smokers. However, questions about the
24 technology's risks and benefits remain

1 unanswered.
2 Did I read that correctly?
3 A. Correct.
4 Q. All right. And this is the National Cancer
5 Institute; correct?
6 A. Correct.
7 Q. But detecting these early tumors has not
8 been proven to reduce the likelihood of dying
9 from lung cancer, the gold standard for any
10 cancer screening test.
11 By the way, you agreed earlier that the gold
12 standard for any screening test is reduced
13 mortality; correct?
14 A. Correct.
15 Q. The National Cancer Institute, NCI,
16 is designing a large study that should
17 conclusively answer whether spiral CT does in
18 fact reduce mortality.
19 Did I read that correct?
20 A. Correct.
21 Q. You are aware of the fact that NCI is in
22 the process of designing and maybe ultimately
23 performing a study to determine if a screening with
24 low-dose CT actually save lives; correct?

1 A. It is probably started already.

2 Q. Okay. But you don't actually know if they
3 have started?

4 A. They have started.

5 Q. They have, okay, good. We will get to that
6 in a minute.

7 Scarring from smoking and other
8 noncancerous changes in the lungs can mimic
9 tumors on CT scans, challenging the
10 radiologists who read them. Interpretations of
11 the scans can vary, leading to confusion about
12 recommendations for follow-up care.
13 Did I read that correctly?

14 A. Correct.

15 MR. WOODSIDE: And could we go further, Jason?
16 Let me see if we can get the rest of the page in.

17 BY MR. WOODSIDE:

18 Q. Christine D. Berg, M.D., cheif of the Lung
19 and Upper Aerodigestive Cancer Research Group
20 at NCI, estimates that 20 percent to 40 percent
21 of CT scans of smokers will show abnormalities
22 that are not cancer.

23 Did I read that correctly?

24 A. Correct.

1 Q. The physician may also advise an immediate
2 lung biopsy, a potentially risky procedure,
3 that involves the removal of a small amount of
4 tissue, either through a scope fed down the
5 windpipe, parentheses, bronchoscopy, closed
6 parentheses, or with a needle through the rib
7 cage, CT-directed needle biopsy, closed
8 parentheses. Possible complications from the
9 biopsies include partial collapse of the lung,
10 bleeding, infection and pain and discomfort.

11 Depending on the size and location of the
12 nodule, chest surgery, thoracotomy to obtain a
13 larger biopsy may be recommended. Thoracotomy
14 is a major surgery that removes substantial
15 amounts of lung tissue. The procedure can
16 damage nerves in the chest and may lead to
17 chronic pain.

18 But recently some hospitals have begun
19 promoting spiral CT scans to smokers for early
20 detection of lung cancer, despite the lack of
21 solid evidence.

22 Did I read those correctly?

23 A. Correct.

24 MR. WOODSIDE: And is that the end of that,

1 Jason?
2 BY MR. WOODSIDE:
3 Q. Okay.
4 But the only proven way to reduce the risk of
5 lung cancer is not to smoke. For people who do
6 smoke, quitting reduces the risk of lung cancer
7 considerably over the course of several years.
8 Did I read that correctly?
9 A. Correct.
10 Q. And you agree with that, don't you?
11 A. Yes.
12 Q. Now, let me go back --
13 MR. WOODSIDE: Could you pull up the entire
14 document on the screen for just a minute, Jason, and
15 go back to the page before.
16 BY MR. WOODSIDE:
17 Q. Now, this is a press release from the
18 National Cancer Institute; correct?
19 A. Correct.
20 Q. Now, I wanted to go back and discuss with
21 you this is the chart which Mr. Furr used during
22 opening statement and which I believe you indicated,
23 as it relates to lung cancer, it was wrong?
24 A. I indicated, yes, the National Cancer

1 Institute -- I indicated most of these no's are
2 based on old data.

3 Q. All right. Now, old data you are talking
4 about is doing screening with chest x, rays which
5 you say is not the standard of care and hasn't been
6 done for years?

7 A. Correct.

8 Q. Maybe even decades?

9 A. Correct.

10 Q. Now, I want to make sure that I understand
11 what you said and what you really mean. You are not
12 suggesting that the National Cancer Institute has
13 said, yes, we should screen with low-dose helical
14 CTs, are you?

15 A. No.

16 Q. So let me go down these. The same would be
17 true for each one of these; correct?

18 A. Correct.

19 Q. So just so we are clear, while you may
20 disagree with how the no's came to be, you would
21 agree with me that the National Cancer Institute has
22 not recommended low-dose CT screening in
23 asymptomatic smokers; correct?

24 A. Correct.

1 Q. And that same would be true for the
2 American Cancer Society?

3 A. Correct.

4 Q. Same would be true for the Society for
5 Thoracic Radiology?

6 A. Yes.

7 Q. And actually, on this whole chart, not one
8 of these organizations would you tell me to put a
9 check mark in the yes box, would you, under lung
10 cancer?

11 A. No.

12 Q. When you say no, you mean, yes, I am
13 correct, you would not say --

14 A. You are correct.

15 Q. Okay. And you and I got caught up in
16 semantics. Let me go back and make sure.

17 You are not suggesting that, under the lung
18 cancer column, I should put a yes or a check mark in
19 the yes box for any one of these, are you?

20 A. Correct.

21 Q. Thank you.

22 MR. WOODSIDE: Jason could you pull up BWB
23 19155?

24 May I approach, Your Honor?

1 THE COURT: Yes.

2 BY MR. WOODSIDE:

3 Q. Now, Doctor --

4 MR. WOODSIDE: Jason, could you blow up the top
5 thing?

6 BY MR. WOODSIDE:

7 Q. I have handed you a document entitled

8 Lung Cancer Mortality In The Mayo Lung

9 Project: The Impact of Extended Follow-up, by
10 Pamela M. Marcus and others; correct?

11 A. Correct.

12 MR. WOODSIDE: And, Jason, if you would go back
13 to the full, and go down to the bottom, pull this
14 up.

15 BY MR. WOODSIDE:

16 Q. This was published in the Journal of the

17 National Cancer Institute on August 16, in the year

18 2000; correct?

19 A. Correct.

20 MR. WOODSIDE: And Jason, could we go to the

21 first highlighted section? Would you pull up the

22 highlighted section?

23 BY MR. WOODSIDE:

24 Q. Now, these researchers were at the National

1 Cancer Institute; correct?
2 A. Correct.
3 Q. If lung cancer lesions with little or no
4 clinical relevance truly exist, spiral CT will
5 identify them at a rate even higher than that
6 of chest x-ray. Before spiral CT is accepted
7 into medical practice, it is critical to
8 determine whether this promising new screening
9 modality ultimately does more good than harm in
10 a randomized, controlled clinical trial with
11 lung cancer mortality as the end point.
12 Did I read that correctly, sir?
13 A. Correct.
14 MR. WOODSIDE: And could I have the next one,
15 Jason which is BWB 23531?
16 May I approach, Your Honor?
17 THE COURT: Yes.
18 BY MR. WOODSIDE:
19 Q. Now, the next publication, one by
20 Dr. Black, is an editorial; correct?
21 A. Correct.
22 Q. And in the scientific publications that you
23 read and some of which you referred to during your
24 direct examination -- strike that.

1 Let me approach it this way. In the medical
2 journals, there are various categories of articles,
3 are there not? Let me tell you where I am going.

4 There can be the reports of scientific studies,
5 there can be editorials, there can be letters to the
6 editor. There are various categories of materials;
7 correct?

8 A. Correct.

9 Q. Okay. And some of the material you have
10 cited to earlier that was blown up is in the
11 category of opinions or editorials; correct?

12 A. Correct.

13 Q. And that's different than a full blown
14 study with the data such as Dr. Henschke reported;
15 correct?

16 A. Correct.

17 Q. Now, I'm going to show you an editorial,
18 and if you would blow up the title, please? This is
19 the title: "Overdiagnosis: An Underrecognized
20 Cause of Confusion and Harm in Cancer Screening," by
21 William C. Black. And could we have the next
22 section, Jason?

23 Overdiagnosis occurs with the detection
24 of, quotation marks, pseudodisease, closed

1 quotation marks, a subclinical condition that
2 would not have produced signs or symptoms
3 before the individual died of other causes.
4 Did I read that correctly?
5 A. Correct.
6 Q. And sir, that reflects the fact that -- I'm
7 going to ask you a very broad question which is a
8 conceptual question, then I will finish this article
9 in a minute.
10 Individuals can die as a result of having a
11 disease; correct?
12 A. Yes.
13 Q. On the other hand, individuals can die with
14 a disease, but it's not -- but the death is not
15 caused by that disease; correct?
16 A. Correct.
17 Q. Overdiagnosis can also occur with detection
18 of a nonmalignant condition that is
19 misclassified as malignant, that is a
20 pathologic false positive error.
21 Did I read that correctly?
22 A. Correct.
23 Q. Next one?
24 For individuals who undergo cancer

1 screening, overdiagnosis is also highly
2 relevant because it is the most serious side
3 effect. False positive results, which have
4 received much more attention, may cause the
5 screenee to worry for months about having a
6 cancer and -- I think it's -- can lead to an
7 invasive procedure, such as a percutaneous
8 needle biopsy in the case of lung cancer
9 screening.
10 Did I read that correctly?
11 A. Correct.
12 MR. WOODSIDE: Could we go to the next one,
13 please?
14 BY MR. WOODSIDE:
15 Q. Overdiagnosis and false positive results
16 could be a much bigger problem with chest CT
17 than they were with chest radiography.
18 Did I read that correctly?
19 A. Correct.
20 Q. And sir, that's because the reason it can
21 be a much bigger problem with chest CT rather than
22 chest x-ray is because you find so many more
23 conditions; correct?
24 A. Correct.

1 MR. WOODSIDE: And let's go to the last one.

2 BY MR. WOODSIDE:

3 Q. Because the potential for overdiagnosis and
4 false positive results will be so great with
5 helical CT, it is essential that there be some
6 mechanism in the screening process to minimize
7 these side effects, such as a mandatory
8 observation period for small nodules.

9 Randomized clinical trials should be performed,
10 and all causes of mortality should be closely
11 monitored to avoid missing a major benefit or
12 harm from the screening process.

13 Did I read that correctly, sir?

14 A. Correct.

15 MR. WOODSIDE: And Jason, would you go back to
16 the first page for a second? And go down to the
17 bottom there. I did not indicate the journal.

18 BY MR. WOODSIDE:

19 Q. That was published in the Journal of the
20 National Cancer Institute, August 16, 2000; correct?

21 A. National Cancer.

22 Q. Would you read it?

23 A. Journal of the National Cancer Institute,
24 dated August 16, 2000.

1 Q. I apologize. Thank you.

2 Now, I ask you a couple questions a few minutes
3 ago about NCI and the American Cancer Society, and I
4 think you indicated that the American Cancer Society
5 is one of the prominent institutions with regard to
6 lung cancer screening and research?

7 A. Correct.

8 Q. Okay. And I do not mean this to be a
9 sarcastic comment.

10 The American Cancer Society is certainly no
11 friend of the tobacco industry; correct?

12 A. Sure.

13 Q. Now, could we go look at BWB 23542?

14 MR. WOODSIDE: May I approach, Your Honor?

15 THE COURT: Sure.

16 MR. WOODSIDE: I was taking some time because I
17 know, this morning, you referred to one publication
18 by the American Cancer Society, and I couldn't
19 remember whether it was this or one or another. I
20 now know it was not this one. I will get to the
21 other one in just a minute.

22 Will you blow up the top here for me for just a
23 minute?

24 BY MR. WOODSIDE:

1 Q. American Cancer Society Guidelines for the
2 Early Detection of Cancer by Robert A. Smith Ph.D.,
3 Curtis J. Mettlin, Ph.D., Cortney Johnston Davis,
4 Ph.D., Harman Eyre, E Y R E, M.D.

5 And here Dr. Smith, director of cancer
6 screening, American Cancer Society, Atlanta,
7 Georgia?

8 Dr. Mettlin is professor of epidemiology at
9 Rosswell Park Cancer Institute, Buffalo New York.

10 Dr. Davis is currently senior scientist, Glaxo-
11 Wellcome, Inc., Research Triangle Park, North
12 Carolina and was an epidemiologist for the ACS.
13 That's the American Cancer Society; correct?

14 A. Correct.

15 Q. Department of Epidemiology and Surveillance
16 research when this article was written.

17 Dr. Eyre is executive vice president of
18 research and medical affairs, American Cancer
19 Society, Atlanta, Georgia.

20 And this article appeared in CA, a cancer
21 journal for clinicians. That's a respectable
22 journal; correct?

23 A. Correct.

24 Q. Next?

1 It is also the case that decisions to
2 engage in testing that has not yet been
3 endorsed may be without merit, wasteful and
4 harmful.

5 Did I read that correctly?

6 A. Correct.

7 Q. Next? Doctor, this journal was published
8 in January and February, 2000. Can you see that at
9 the bottom?

10 A. Correct.

11 Q. Correct?

12 A. Correct.

13 Q. Now, I will go to the section of this
14 publication dealing with lung cancer.

15 At this time -- and by the way, this is the
16 American Cancer Society guidelines; correct?

17 A. Correct.

18 Q. Lung cancer. At this time, no organization
19 recommends routine screening for lung cancer
20 either among the general adult population or in
21 individuals who are at higher risk due to
22 tobacco or occupational exposures.

23 Did I read that correctly, sir?

24 A. Correct.

1 Q. Next?

2 In spite of the limitations of existing
3 data, it is generally accepted that lung cancer
4 screening is not effective. Whereas it would
5 be more appropriate to regard the current
6 evidence-based situation as one in which there
7 are insufficient data to recommend for or
8 against lung cancer screening.

9 Next?

10 ACS recommendations.

11 That would be American Cancer Society
12 recommendations; correct?

13 A. Correct.

14 Q. At this time, the ACS or American
15 Cancer Society does not recommend routine
16 screening for lung cancer among the general
17 adult population or in individuals who are at
18 higher risk due to tobacco or occupational
19 exposures.

20 Did I read that correctly?

21 A. Correct.

22 MR. WOODSIDE: Would this be a convenient place
23 to stop?

24 THE COURT: Yeah, I think so. I think we can

1 break now for the noon lunch break. Please don't
2 discuss the case among yourselves, nor permit
3 anybody to discuss it with you. We will see you
4 back here at 1:00.

5 Doctor, you obviously can go and have some
6 lunch.

7 THE WITNESS: Thank you.

8 THE COURT: The only thing I will ask you,
9 please do not discuss your testimony with anyone, as
10 you are still on the witness stand; all right, sir?

11 THE WITNESS: Thank you.

12 (A luncheon recess is taken at 11:57 a.m.)

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